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Proposed Registration Decision PRD2015-22

Oxathiapiprolin

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Overview

Proposed Registration Decision for Oxathiapiprolin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of DuPont Zorvec Technical Fungicide, Dupont Zorvec Enicade Fungicide, Dupont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide, containing the technical grade active ingredient oxathiapiprolin, for use against selective oomycete diseases on bulb vegetables, brassica (cole) leafy vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, ginseng, tobacco, succulent shelled and edible-podded peas, and potatoes.

Dupont Zorvec Enicade Fungicide and Orondis Fungicide are proposed oil dispersion (OD) formulations applied to soil or as a foliar spray to control downy mildew and phytophthora diseases. Dupont Zorvec Epicaltrin Fungicide and OXTP 200SC Fungicide are suspension concentrate (SC) formulations that are proposed for use as soil applied products to control certain phytophthora diseases.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of DuPont Zorvec Technical Fungicide, Dupont Zorvec Enicade Fungicide, Dupont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide, containing the technical grade active ingredient oxathiapiprolin.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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[1] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

[2] "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on oxathiapiprolin, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on oxathiapiprolin, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Oxathiapiprolin?

Oxathiapiprolin is a new conventional fungicide active ingredient that prevents spore initiation and inhibits growth in susceptible fungi. It represents a new mode of action not previously available to Canadian growers.

Health Considerations

Can Approved Uses of Oxathiapiprolin Affect Human Health?

Products containing oxathiapiprolin are unlikely to affect your health when used according to label directions.

Potential exposure to oxathiapiprolin may occur through the diet (food and water) or when handling and applying the products. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

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[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

In laboratory animals, the technical grade active ingredient (oxathiapiprolin) was of low acute toxicity by the oral, dermal and inhalation routes. It was non-irritating to skin, minimally irritating to eyes and did not cause an allergic skin reaction.

The acute toxicity of the oil dispersion (OD) end-use products, Orondis Fungicide and Dupont Zorvec Enicade Fungicide, was low via the oral, dermal and inhalation routes of exposure. The products were non-irritating to the eyes and moderately irritating to the skin. They caused allergic skin reactions; consequently, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on their labels.

The acute toxicity of the suspension concentrate (SC) end-use products, OXTP 200SC Fungicide and Dupont Zorvec Epicaltrin Fungicide, was low via the oral, dermal and inhalation routes of exposure. They were non-irritating to the eyes and skin and did not cause an allergic skin reaction.

Short- and long-term (lifetime) animal toxicity tests were assessed for the potential of oxathiapiprolin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were decreased body weight and body-weight gain and delayed sexual maturation in males. There was an indication that the young were more sensitive than the adult animal. The risk assessment protects against the findings noted above as well as any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and infants less than one year old, the subpopulation which would ingest the most oxathiapiprolin relative to body weight, are expected to be exposed to less than or equal to 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from oxathiapiprolin is not of health concern for all population subgroups.

Oxathiapiprolin is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

Animal studies revealed no relevant health effects for acute dietary risk assessment. Consequently, a single dose of oxathiapiprolin is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for The *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using oxathiapiprolin on potatoes, dry bulb onions, green onions, head lettuce, leaf lettuce, spinach, broccoli, cabbage, cauliflower, tomatoes, peppers, cucumbers, summer squash, cantaloupe, succulent peas and ginseng are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Occupational Risks From Handling DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide are not of health concern when used according to the proposed label directions, which include protective measures.

Workers, who mix, load or apply DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, or OXTP 200SC Fungicide, can come in direct skin contact with oxathiapiprolin residues or through inhaling spray mists during mixing/loading and application. Furthermore, workers re-entering freshly treated fields and greenhouses can come in direct skin contact with DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide residues from the treated foliage. Therefore, the OXTP 200SC Fungicide and Dupont Zorvec Epicaltrin Fungicide labels specify that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks. The Orondis Fungicide and Dupont Zorvec Enicade Fungicide labels specify that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt and long pants, coveralls, chemical-resistant gloves, and chemical-resistant footwear plus socks. The labels also require that no one can enter treated areas for 12 hours after application.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Oxathiapiprolin Is Introduced into the Environment?

When used according to label directions, oxathiapiprolin is not expected to pose an unacceptable risk to the environment.

Oxathiapiprolin can enter the environment when it is used as a fungicide for the control of oomycete diseases in a variety of field vegetable crops. It can be applied directly to plants as a foliar spray or as a soil drench, but not as both on the same crop. Oxathiapiprolin can enter into plant tissues and be distributed throughout the plant because it is systemic.

In the terrestrial environment in Canada, oxathiapiprolin can persist in the environment and has a potential to carryover to the following growing season. Breakdown of the molecule is predominantly by soil microbes which produce three major transformation products which can persist in soil. Oxathiapiprolin does not readily break down by reacting with water or sunlight. Oxathiapiprolin and two of the three major transformation products have limited potential to move through the soil to enter groundwater. One transformation product has the potential to move through soil, but was not found beyond 70 cm in depth in North American field studies. Oxathiapiprolin is not volatile and is unlikely to enter the atmosphere.

In the aquatic environment, oxathiapiprolin breaks down primarily in the presence of microbes. It does not react with water and has a limited potential to break down by reacting with sunlight in water. In water, oxathiapiprolin will move to sediments where it will be broken down by microbes. Several major transformation products were observed in water and sediments. In general, once oxathiapiprolin enters the aquatic environment it will begin to breakdown and is unlikely to be persistent in water and sediments.

Oxathiapiprolin is not expected to accumulate in fish tissues.

Overall, oxathiapiprolin and its major transformation products are not expected to pose a risk to soil-dwelling invertebrates, birds, mammals, terrestrial and aquatic plants, algae, aquatic invertebrates and fish (freshwater and marine). Plant-dwelling invertebrates within treated fields may be at risk from oxathiapiprolin at rates greater than 200 g a.i./ha. Oxathiapiprolin may present a slight risk to amphibians living in shallow water. In order to minimize the potential risk of oxathiapiprolin to terrestrial and aquatic organisms, precautionary label statements as well as mitigation measures are specified on the labels of the end use products (refer to Measures to Minimize Risk). When oxathiapiprolin is used in accordance with the label and the mitigation measures have been applied, the reduced environmental exposure is deemed adequate and the risk is considered to be acceptable.

Value Considerations

What Is the Value of DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide?

These oxathiapiprolin products provide a new mode of action for growers to manage downy mildew and diseases caused by *Phytophthora* species on multiple field and greenhouse crops.

The registration of oxathiapiprolin will address several priority diseases identified by Canadian growers. As a new mode of action fungicide that is effective against difficult to control oomycete fungi, oxathiapiprolin will contribute to protecting the quality of labelled crops and reducing the development of resistance in susceptible fungi while allowing alternation with other products currently registered for the same use.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of DuPont *Zorvec* Technical Fungicide, DuPont *Zorvec* Enicade Fungicide, DuPont *Zorvec* Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct skin contact with DuPont *Zorvec* Enicade Fungicide, DuPont *Zorvec* Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide or through inhalation of spray mists, the OXTP 200SC Fungicide and Dupont *Zorvec* Epicaltrin Fungicide labels specify that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks. The Orondis Fungicide and Dupont *Zorvec* Enicade Fungicide labels specify that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt and long pants, coveralls, chemical-resistant gloves, and chemical-resistant footwear plus socks. The labels also require that no one can enter treated areas for 12 hours after application.

Environment

- Environmental hazard statements are required to indicate toxicity to aquatic organisms.
- Dupont *Zorvec* Enicade Fungicide and Orondis Fungicide labels require a hazard statement indicating that the product contains an aromatic petroleum distillate which is toxic to aquatic organisms.
- To mitigate potential exposure of amphibians through spray drift, spray buffer zones of 1 to 2 metres are required to protect sensitive aquatic habitats for foliar applications and must be specified on the labels of DuPont *Zorvec* Enicade Fungicide and Orondis Fungicide.
- Instructions for reducing run-off are required on the labels of all proposed end use products.
- Environmental hazard statements to indicate potential harm to beneficial invertebrates in fields receiving foliar applications at rates over 200 g a.i./ha are required.
- To minimize the potential of oxathiapiprolin to be carried over to the following growing season, a label statement informing the users of the carry-over potential of this chemical is to be specified on the labels of the proposed end use products.

Next Steps

Before making a final registration decision on oxathiapiprolin, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the *Agency's* response to these comments.

Other Information

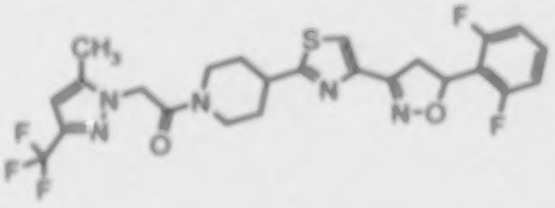
When the PMRA makes its registration decision, it will publish a Registration Decision on oxathiapiprolin (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Oxathiapiprolin

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Oxathiapiprolin
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	PIN (preferred IUPAC name): *rac*-1-(4-{4-[(5*R*)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethan-1-one *or* 1-(4-{4-[(5*RS*)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}-1-piperidyl)-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone
2. Chemical Abstracts Service (CAS)	1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]-ethanone
CAS number	1003318-67-9
Molecular formula	$C_{24}H_{22}F_5N_5O_2S$
Molecular weight	539.5 g/mol
Structural formula	
Purity of the active ingredient	97%

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Oxathiapiprolin Technical

<table>
<tr><th>Property</th><th>Result</th></tr>
<tr><td>Colour and physical state</td><td>Off-white solid</td></tr>
<tr><td>Odour</td><td>None</td></tr>
<tr><td>Melting point</td><td>For the pure active ingredient: 146.4 ± 0.2°C.
For the technical grade active ingredient: 138.7 ± 0.2°C.</td></tr>
<tr><td>Boiling point</td><td>None noted, as the product decomposed after melting.</td></tr>
<tr><td>Relative density at 20°C</td><td>For the pure active ingredient: 1.4645 ± 0.007.
For the technical grade active ingredient: 1.4684 ± 0.018.</td></tr>
<tr><td>Vapour pressure at 20°C</td><td>1.141×10^{-6} Pa (by extrapolation)</td></tr>
<tr><td>Henry's law constant at 20°C</td><td>3.521×10^{-3} Pa m^3/mol</td></tr>
<tr><td>Ultraviolet (UV)-visible spectrum</td><td><table>
<tr><th>pH</th><th>λ_{max}</th><th>ε (L/mol.cm)</th></tr>
<tr><td>1.8</td><td>257-258</td><td>14055</td></tr>
<tr><td>7</td><td>256-257</td><td>13863</td></tr>
<tr><td>10.5</td><td>258-259</td><td>16384</td></tr>
</table></td></tr>
<tr><td>Solubility in water at 20°C</td><td><table>
<tr><th>pH</th><th>Solubility (µg/mL)</th></tr>
<tr><td>Milli-Q water</td><td>0.1749</td></tr>
<tr><td>4</td><td>0.2111</td></tr>
<tr><td>7</td><td>0.1844</td></tr>
<tr><td>9</td><td>0.2060</td></tr>
</table></td></tr>
<tr><td>Solubility in organic solvents at 20°C</td><td>For the pure active ingredient:<table>
<tr><th>Solvent</th><th>Solubility (g/L at 20°C ± 0.5°C)</th></tr>
<tr><td>Acetonitrile</td><td>111.0 ± 3.9</td></tr>
<tr><td>Methanol</td><td>13.0 ± 0.5</td></tr>
<tr><td>Acetone</td><td>147.3 ± 6.1</td></tr>
<tr><td>Ethyl acetate</td><td>31.7 ± 2.1</td></tr>
<tr><td>Dichloromethane</td><td>347.3 ± 9.2</td></tr>
<tr><td>Toluene</td><td>5.7 ± 0.2</td></tr>
<tr><td>n-Octanol</td><td>0.04 ± 0.00</td></tr>
<tr><td>n-Hexane</td><td>0.01 ± 0.00</td></tr>
</table></td></tr>
<tr><td>*n*-Octanol-water partition coefficient (K_{ow})</td><td><table>
<tr><th>pH of water</th><th>log K_{ow}</th></tr>
<tr><td>Milli-Q water</td><td>3.66</td></tr>
<tr><td>4</td><td>3.62</td></tr>
<tr><td>7</td><td>3.67</td></tr>
<tr><td>9</td><td>3.64</td></tr>
</table></td></tr>
</table>

Property	Result
Dissociation constant (pK_a)	No dissociation observed from pH 1.0-9.1.
Stability (temperature, metal)	Stable at elevated temperature (54°C for 14 days) and in contact with metals (aluminum and iron) and metal ions (aluminum acetate and iron(II) acetate).

End-Use Products

Property	DuPont Zorvec Enicade Fungicide	DuPont Zorvec Epicaltrin Fungicide
Colour	Off-white	White opaque
Odour	Moderate oily characteristic odour	Chemical odour
Physical state	Liquid	Liquid
Formulation type	Oil dispersion (PMRA formulation type = suspension)	Suspension concentrate (PMRA formulation type = suspension)
Guarantee	100 g/L	200 g/L
Container material and description	0.5 – 1500 L HDPE plastic	1 – 1500 L HDPE plastic
Relative density	0.987	1.0697
pH of 1% dispersion in water	6.5	6.7
Oxidizing or reducing action	Not oxidizing or reducing	Not oxidizing or reducing
Storage stability	Stable after storage for 14 days at 54°C	Stable after storage for 14 days at 54°C
Corrosion characteristics	Not corrosive to its commercial packaging	Not corrosive to its commercial packaging
Explodability	Not explosive	Not explosive

Property	Orondis Fungicide	OXTP 200SC
Colour	Off-white	White opaque
Odour	Moderate oily characteristic odour	Chemical odour
Physical state	Liquid	Liquid
Formulation type	Oil dispersion (PMRA formulation type = suspension)	Suspension concentrate (PMRA formulation type = suspension)
Guarantee	100 g/L	200 g/L
Container material and description	0.5 – 1500 L HDPE plastic	1 – 1500 L HDPE plastic
Relative density	0.987	1.0697
pH of 1% dispersion in water	6.5	6.7
Oxidizing or reducing action	Not oxidizing or reducing	Not oxidizing or reducing

Property	Orondis Fungicide	OXTP 200SC
Storage stability	Stable after storage for 14 days at 54°C	Stable after storage for 14 days at 54°C
Corrosion characteristics	Not corrosive to its commercial packaging	Not corrosive to its commercial packaging
Explodability	Not explosive	Not explosive

1.3 Directions for Use

Dupont Zorvec Enicade Fungicide and Orondis Fungicide may be applied to foliage using field sprayers or to soil at plant in-furrow or in transplant water, or via drip irrigation. Epicaltrin Fungicide and OXTP 200SC Fungicide are intended for soil application only.

Foliar: Application rates for listed diseases and crops range between 8.75 – 35 g active a.i./ha with re-application intervals of five to 14 days. Rates for phytophthora root rot and foliar blight on ginseng are 70 – 280 g a.i./ha applied on a seven to 14 day interval. The product should be applied prior to disease development. Higher rates and longer intervals should be used when disease pressure is high. The maximum seasonal application rate for foliar application is 140 g a.i./ha, with the exception of ginseng which is 560 g a.i./ha.

Soil applied (drench, chemigation, in-furrow): Application rates for the soil phase of phytophthora blight on cucurbits, tomato, pepper and eggplant are 70 – 280 g a.i./ha to be applied on a minimum application interval of seven days. Higher rates and longer intervals should be used in heavier soils, longer intervals or for susceptible varieties. The maximum seasonal application rate for soil application is 560 g a.i./ha.

1.4 Mode of Action

Oxathiapiprolin inhibits the oxysterol binding protein, which prevents spore germination and inhibits germ tube formation and mycelial growth. This fungicide also induces spore collapse and death. It is currently listed as a group U15 fungicide, with a medium to high risk of resistance development.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredient in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

2.3 Methods for Residue Analysis

High-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices. The proposed enforcement methods were successfully validated in plant and animal matrices by an independent laboratory. Adequate extraction efficiencies were demonstrated using radiolabelled crop samples analyzed with the enforcement method. Extraction solvents used in the method were similar to those used in the animal metabolism studies; thus, further demonstration of extraction efficiency was not required for the analytical method for animal matrices.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for oxathiapiprolin was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to oxathiapiprolin.

Absorption of a single gavage low dose of isoxazoline or pyrazole ring-radiolabelled oxathiapiprolin was moderate in rats. Saturation of absorption was evident with very low absorption in rats following a single high dose. Oxathiapiprolin and its metabolites were readily excreted by the rat after low- and high-dose administration, with fecal excretion as the major route of elimination for all animals. Expiration as carbon dioxide or other volatile compounds was not a significant route of elimination. Retention of oxathiapiprolin or its metabolites in tissues and blood was negligible, indicating low potential for bioaccumulation. Concentrations in individual tissues were at trace levels by 168 hours after dose administration.

The metabolism of oxathiapiprolin involved multiple reaction sites including hydroxylation in various positions. The multiple reactions resulted in many identified and tentatively identified low level metabolites in feces, urine, and bile. Unmetabolized oxathiapiprolin was the chief component recovered in feces and accounted for 17-87% of the administered low- or high-dose of either radiolabel.

Toxicokinetics and metabolism were also examined with multiple, repeat-doses of oxathiapiprolin for 14 days. Similarities between peak and minimum plasma and tissue concentrations across time following single doses suggest steady-state kinetic behaviour in male and female rats. After cessation of dosing, the ^{14}C residues were readily eliminated from tissues and plasma. The overall tissue distribution in male and female rats was similar to that found after single dose administration and indicated low potential for accumulation. Feces was the predominant route of elimination, with urinary elimination of cleaved metabolites playing a minor role. Parent oxathiapiprolin was the primary radiolabeled component in feces.

Metabolism of the systemically absorbed dose was extensive and characterized by numerous identified and tentatively identified components in feces, urine and plasma. The material balance and profile of metabolites were consistent with that observed in the single dose study. Tissue-to-plasma ratios and low levels of total radioactive residues in the fat and other tissues showed no significant potential for bioaccumulation of oxathiapiprolin or its metabolites.

The acute toxicity of oxathiapiprolin was low via the oral, dermal and inhalation routes in rats. It was non-irritating to skin and minimally irritating to eyes of rabbits. Oxathiapiprolin was not a skin sensitizer in guinea pigs by the Maximization method.

The acute toxicity of the end-use products Orondis Fungicide and Dupont Zorvec Enicade Fungicide was low via the oral, dermal and inhalation routes in rats. They were non-irritating to the eyes and moderately irritating to the skin of rabbits. They were skin sensitizers in guinea pigs by the Maximization method.

The acute toxicity of the end-use products OXTP 200SC Fungicide and Dupont Zorvec Epicaltrin Fungicide was low via the oral, dermal and inhalation routes in rats. They were non-irritating to the eyes and skin of rabbits. They were not skin sensitizers in guinea pigs by the Maximization method.

Repeat dose feeding studies with oxathiapiprolin for periods of up to two years in mice, rats and dogs revealed no toxicologically significant effects up to limit doses of testing. A 28-day repeat dose dermal toxicity study in rats produced no systemic toxicity up to the limit dose of testing.

There was no evidence of mutagenic or clastogenic potential of oxathiapiprolin observed in the genotoxicity battery of studies, which included an Ames assay, an in vitro human lymphocyte clastogenicity assay, a Chinese hamster ovary cell gene mutation assay and an in vivo mouse micronucleus assay.

In a dietary multi-generation rat reproductive toxicity study, there was no parental toxicity up to the limit dose of testing. At the highest dose tested, the offspring of the F_2 generation exhibited decreased body weight gains between birth and post-natal day (PND) 21. An increased time to preputial separation was also noted in young males in both generations at the limit dose. The young animals demonstrated an increased sensitivity to oxathiapiprolin in this study.

In rat and rabbit oral gavage developmental toxicity studies, there were no adverse effects noted in adults or developing fetuses up to the limit dose of testing.

Functional observational batteries for neurotoxicity in rat repeat dose dietary toxicity studies were negative. In the rat acute neurotoxicity study, there were no adverse effects observed up to the limit dose of testing.

In a mouse dietary 28-day immunotoxicity study with oxathiapiprolin, there was no evidence of changes to humoral immune function or changes to spleen or thymus weight.

Several metabolites of oxathiapiprolin were tested in a battery of genotoxicity studies and a single metabolite (IN-E8S72) was tested in a dietary short-term toxicity study in rats. None of the metabolites produced effects of concern and none provided evidence that they could be more toxic than the parent molecule.

Results of the toxicology studies conducted on laboratory animals with the end-use product Orondis Fungicide, Dupont Zorvec Enicade Fungicide, OXTP 200SC Fungicide, and Dupont Zorvec Epicaltrin Fungicide and technical active oxathiapiprolin are summarized in Tables 2 and 3, respectively, of Appendix I. The toxicology endpoints for use in the human health risk assessment are summarized in Table 3, Appendix I.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents to the PMRA, including adverse effects on Canadian health or the environment. Incidents were searched for the active ingredient oxathiapiprolin. Oxathiapiprolin is a new active ingredient pending registration for use in Canada. No human or domestic animal incidents involving the active ingredient oxathiapiprolin have been reported to the PMRA.

3.1.1 PEST CONTROL PRODUCTS ACT Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the standard complement of required studies was available including developmental toxicity studies in rats and rabbits and a two-generation dietary reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, there were no effects on fetuses up to and including the limit dose of testing in rats and rabbits. There were post-natal decreases in body weight and body weight gain in F_2 offspring in the rat reproductive toxicity study. Delays in preputial separation were also observed in both generations, but only at the limit dose.

Overall, the database is adequate for determining the sensitivity of the young. The effects on offspring in the reproductive toxicity, although occurring in the absence of maternal toxicity, were themselves not considered serious endpoints and occurred only at the limit dose of testing. The PEST CONTROL PRODUCTS ACT factor was accordingly reduced to 1-fold.

3.2 Acute Reference Dose (ARfD) for all populations

No acute endpoints of concern were identified in the toxicology database, therefore an ARfD was not established.

3.3 Acceptable Daily Intake (ADI) for all populations

To estimate risk from repeated dietary exposure, the rat 2-generation dietary reproductive toxicity study with a NOAEL of 411 mg/kg bw/day was selected for risk assessment. The LOAEL of 1196 mg/kg bw/day was based on decreased offspring body weight and body weight gain during the post-natal period and increased time to preputial separation. This study provides the lowest NOAEL in the database and was considered the most appropriate for the risk assessment. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. As discussed in the PEST CONTROL PRODUCTS ACT Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. The CAF is thus 100.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{411 \text{ mg/kg bw/day}}{100} = 4 \text{ mg/kg bw/day of oxathiapiprolin}$$

Cancer Assessment

There was no treatment-related increase in tumours in rats or mice; therefore, a separate cancer risk assessment was not required.

3.4 Occupational Risk Assessment

Short, Intermediate and Long-term Dermal Exposure

Due to a lack of toxicological effects in the short-term repeat dose dermal toxicity study in rats up to the limit dose of testing, low dermal absorption values and the low concern for effects at the limit dose of testing in the dietary/gavage toxicity studies, dermal exposure endpoints were not selected.

Short- and Intermediate-term Inhalation Exposure

For short- and intermediate-term exposure via the inhalation route, the dietary 2-generation reproductive toxicity study in rats was selected for risk assessment. An offspring NOAEL of 411 mg/kg bw/day was established based on decreased body weight and body weight gain in the post-natal period and increased time to preputial separation. A short-term inhalation study was not available and would not have addressed the endpoint of concern due to protocol design.

In the absence of evidence to the contrary, absorption by the inhalation route is generally assumed to be 100%. In the case of oxathiapiprolin, toxicokinetic data suggest that uptake via the gastro-intestinal tract is very low at high dose levels (approximately 5%). Therefore, a 5% route-to-route correction factor was applied to derive an offspring systemic NOAEL of 20 mg/kg bw/day for short-term and intermediate-term inhalation risk assessment.

The target MOE selected for this endpoint is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability.

3.4.1 Toxicological Endpoints

Workers who mix/load and apply DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide are expected to be exposed for up to 180 days per year (short to intermediate-term exposure duration) since the products are applied up to 6 times per season. Workers entering treated fields and greenhouses are expected to have short to long-term exposure since the products are not expected to dissipate and there is the potential for exposure throughout the entire duration of the crop cycle.

3.4.1.1 Dermal Absorption

The dermal absorption of oxathiapiprolin was determined by an *in vivo* dermal absorption study. The study was conducted on Sprague-Dawley rats using [^{14}C]oxathiapiprolin (purity >98 %). The rate and extent of absorption of radioactivity was investigated following topical application of radiolabelled oxathiapiprolin as a nominal 0.7 g oxathiapiprolin/L aqueous dilution and as the undiluted concentrate at 100 g oxathiapiprolin/L. Only one exposure duration (6 hours) was tested, which is considered to be a minor limitation of the study since it is unclear if different lengths of exposure could result in different levels of absorption. In addition, only two termination times were tested (0 hour post-exposure and 498 hours post-exposure). Recovery of oxathiapiprolin for individual subjects ranged from 94 – 98% and no corrections for incomplete recovery were made since total recovery was acceptable. However, given the uncertainty of the amount of skin removed by each tape strip, the PMRA considers all the tape strips as a uniform layer of *stratum corneum*. For both the low and the high dose groups (7 µg/cm^2 & 1000 µg/cm^2) the residues in excreta increased with increased time; 0.112% (LD), 0.312% (HD) & 3.019% (LD), 1.782% (HD) at 0 hour and 498 hours post-exposure, respectively.

The amount in the *stratum corneum* decreased with time; 7.82% (LD), 12.52% (HD) & 1.22% (LD), 3.49% (HD) at 0 hour and 498 hours post-exposure, respectively, which indicates that the amount found in the *stratum corneum* does become systemically absorbed with time. Therefore, all the tape strips were considered absorbable and the dermal absorption values for the high and low dose groups were 13% & 5% and 8% & 4% at 0 hour and 498 hours post-exposure, respectively.

3.4.2 Occupational Exposure and Risk

Exposure to workers who mix/load and apply DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide on bulb vegetables, brassica leafy vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, ginseng, tobacco, succulent peas, and potatoes are expected to be exposed for up to 180 days per year (short to intermediate-term exposure duration) since the products are applied up to 6 times per season. Workers entering treated fields and greenhouses are expected to have short to long-term exposure since the products are not expected to dissipate and there is the potential for exposure throughout the entire duration of the crop cycle.

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Individuals have potential for dermal and inhalation exposure to DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide during mixing, loading and application. However, since there are no dermal endpoints due to a lack of toxicity (See section 3.4), only an inhalation risk assessment is required. Inhalation exposure estimates for workers open mixing & loading and applying using backpack, manually-pressurized handwand and mechanically-pressurized handgun were generated from PHED version 1.1.

Exposure to workers mixing, loading and applying DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide is expected to be short-term to intermediate-term in duration and to occur primarily by the inhalation routes. Exposure estimates were derived for mixers/loaders/applicators applying Orondis Fungicide and DuPont Zorvec Enicade Fungicide to greenhouse cucumbers, tomatoes, and peppers using backpack, manually-pressurized handwand and mechanically-pressurized handgun and for mixers/loaders/applicators applying DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide to bulb vegetables, brassica leafy vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, ginseng, tobacco, succulent peas, and potatoes using open-cab groundboom. The exposure estimates are based on mixers/loaders/applicators wearing a single layer of clothing plus gloves for all application methods.

Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints from section 3.4.1 (NOAEL: no observed adverse effects level) to obtain the margin of exposure (MOE) in Table 3.4.2.1.1; the target MOE is 100 for inhalation exposure. No risks of concern were identified when workers followed the recommended precautions on the label.

Note that although there were no dermal health risks of concern identified for mixers/loaders/applicators wearing a single layer of clothing plus gloves for all application methods, there are potential acute dermal hazards (skin sensitizer) from handling Orondis Fungicide and Dupont Zorvec Enicade Fungicide (Section 3.1) and mixers/loaders/applicators are required to wear coveralls as a result (see Measures to Minimize Risk).

Table 3.4.2.1.1: Mixer/Loader/Applicator Inhalation Exposure Estimates and MOE

Exposure scenario	Maximum application rate (kg a.i./ha)	Volume handled per day (litres)	Area treated per day (ha/day)	Inhalation exposure[1] (mg/kg bw/day)	Inhalation MOE (target 100)[2]
Groundboom, Open mixing/loading/applying (also covers chemigation, in-furrow or banded application)	0.28	N/A	360	0.0003	6,700
Backpack/Manually-pressurized handgun	0.035	150 L	1.36[3]	0.000003	541,300
Mechanically-pressurized handgun	0.035	3800 L	34.54[3]	0.000228	8,700

[1] Daily exposure = (PHED unit-exposure × rate × spray (volume/day / dilution rate) × 0.001 kg/g × 0.001mg/µg) / 80 kg bw)

[2] Margin of Exposure (MOE) = NOAEL $_{\text{(route-specific)}}$ / Exposure

[3] Based on the minimum dilution rate of 110 L/ha

* Exposure was estimated for workers wearing a single layer plus gloves.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with DuPont *Zorvec* Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide to perform various activities including hand pruning, scouting, hand harvesting and handline irrigation. Given the nature of activities performed, dermal contact with treated surfaces is expected to occur throughout the season. However, since there are no dermal endpoints selected, a dermal exposure assessment is not required. Inhalation exposure is not expected to occur since workers and bystanders are not allowed to enter until 12 hours after application and the vapour pressure of oxathiapiprolin is estimated to be 1.4×10^{-9} kPa at 25°C. This vapour pressure is less than the NAFTA waiver for an inhalation study of $<1 \times 10^{-5}$ kPa (7.5×10^{-5} mmHg) for indoor uses, and $<1 \times 10^{-4}$ kPa (7.5×10^{-4} mmHg) for outdoor uses at 20-30°C.

3.4.3.3 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products and animal commodities is oxathiapiprolin. The data gathering/enforcement analytical method is valid for the quantitation of oxathiapiprolin residues in crop and livestock matrices. The residues of oxathiapiprolin are stable in representative matrices from five crop categories (high water, high oil, high protein, high starch and high acid content) for up to 18 months when stored at -20°C. Therefore, oxathiapiprolin residues are considered stable in all frozen crop matrices and processed crop fractions for up to 18 months. Oxathiapiprolin residues concentrated in the following processed commodities: dried tomatoes (6.9x) and raisins (1.5x). Quantifiable residues are not expected to occur in livestock matrices with the current use pattern. Crop field trials conducted throughout Canada and the United States using end-use products containing oxathiapiprolin at approved rates in or on potatoes, dry bulb onions, green onions, head lettuce, leaf lettuce, spinach, broccoli, cabbage, cauliflower, tomatoes, peppers, cucumbers, summer squash, cantaloupe, succulent peas and ginseng are sufficient to support the proposed maximum residue limits.

3.5.2 Dietary Risk Assessment

A chronic (non-cancer) dietary risk assessment was conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™), which incorporates food consumption data from the National Health and Nutritional Examination Survey, What We Eat in America (NHANES/WWEIA) dietary survey available through CDC's National Center for Health Statistics (NCHS).

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic non-cancer analysis for oxathiapiprolin: 100% crop treated, default processing factors, residues of crop and animal commodities based on recommended MRL values. The basic chronic dietary exposure from all supported oxathiapiprolin food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 1% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to oxathiapiprolin from food and drinking water is <1% (0.0162 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for all infants (<1 year) at 1% (0.0808 mg/kg bw/day) of the ADI.

3.5.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified.

3.5.2.3 Exposure from Drinking Water

Concentrations in Drinking Water

Estimated environmental concentrations (EECs) for the combined residue of oxathiapiprolin and its major transformation products in potential drinking water sources (groundwater and surface water) were generated using computer simulation models. An overview of how the EECs are estimated is provided in the PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*. EECs of oxathiapiprolin in groundwater were calculated using the PRZM-GW model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using PRZM-GW are average concentrations in the top one metre of the water table. EECs of oxathiapiprolin in surface water were calculated using the PRZM/SWCC models, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in a vulnerable drinking water source, a small reservoir.

There are more than ten transformation products in the environment for oxathiapiprolin. Very little information is available regarding their health concerns, and therefore, to be conservative, nine of the transformation products were included in the screen level modelling for drinking water from sources of surface water. The surface water residue definition includes the parent oxathiapiprolin and its transformation products- IN-RAB06, IN-RDT31, IN-Q7D41, IN-S2K66, IN-RM101, IN-RVF72, IN-S2K67, IN-QFD61, whereas the groundwater modelling residue definition includes oxathiapiprolin and its transformation products- IN-RAB06, IN-RDT31, IN-E8S72. The residue definition was based on the properties of the residues including their mobility in soil, persistence in the environment, where they are formed (in soil or in water), and the maximum residue levels observed in the fate studies, as well as their toxicity to human health. In the current assessment, the combined residue was modelled for drinking water. Thus environmental half-lives in soil and water were calculated for the combined residues.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. The Level 1 EEC estimate is expected to allow for future use expansion into other crops at this application rate. Several initial application dates between April and September were modelled. The model was run to simulate a period of 50 years for all scenarios. The largest EECs of all selected runs are reported in Table 3.5.2.3-1 below.

Table 3.5.2.3-1: Level 1 estimated environmental concentrations (parent equivalent) of the combined residue of oxathiapiprolin and major transformation products in potential drinking water sources.

Crop	Groundwater EECs (µg a.i./L)			Surface Water EECs (µg a.i./L)		
	Daily[1]	Yearly[2]	PBT average[3]	Daily[4]	Yearly[5]	Average[6]
potatoes, tomatoes (field), squash (field), peas, onions (all), ginseng, cucumbers (field) and pumpkins (field)	711	507	370	12	3.9	3.3

1 90th percentile of daily average concentrations
2 90th percentile of yearly average concentrations
3 post-breakthrough average concentration
4 90th percentile of yearly peak concentrations
5 90th percentile of yearly average concentrations
6 50-year simulation average concentration

3.5.3 Aggregate Exposure and Risk

The aggregate risk for oxathiapiprolin consists of exposure from food and drinking water sources only; there are no residential uses.

3.5.4 Maximum Residue Limits

Table 3.5.4-1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Leafy Greens (Crop Subgroup 4-13A)	15
Dried tomatoes	2.0
Green Onion (Crop Subgroup 3-07B)	2.0
Brassica Head and Stem Vegetables (Crop Group 5-13)	1.5
Edible podded dwarf peas	1.0
Edible podded peas	1.0
Edible podded snow peas	1.0
Edible podded sugar snap peas	1.0
Fruiting Vegetables (Crop Group 8-09)	0.5
Cucurbit Vegetables (Crop Group 9)	0.2
Ginseng roots	0.15
Succulent shelled English peas	0.05
Succulent shelled garden peas	0.05

Succulent shelled green peas	0.05
Succulent shelled peas	0.05
Bulb Onion (Crop Subgroup 3-07A)	0.04
Tuberous and Corm Vegetables (Crop Subgroup 1C)	0.01
Milk, fat, meat and meat byproducts of cattle, goats, horses, hogs and sheep	0.01

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

For additional information on Maximum Residue Limits (MRLs) in terms of the international situation and trade implications, refer to Appendix II.

The nature of the residues in animal and plant matrices, analytical methodologies, field trial data, and chronic dietary risk estimates are summarized in Tables 5, 6 and 7 in Appendix I.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Oxathiapiprolin is only sparingly soluble in water and exists in neutral form in the environmentally relevant pH range. It adsorbs strongly and has very low mobility in soils. Chemical processes including volatilization, phototransformation and hydrolysis do not contribute to the overall dissipation of oxathiapiprolin. Oxathiapiprolin has the potential to bioacccumulate in fish (log K_{ow} of 3.6); however laboratory studies show bioaccumulation is not a concern.

In the terrestrial environment in North America, oxathiapiprolin is moderately persistent to persistent. Three major transformation products, IN-RDT31, IN-RAB06, and IN-E8S72 were moderately persistent or persistent in laboratory studies with aerobic soils (all three were less than or equal to 13.5% of applied radioactivity). A minimal amount of mineralization to CO_2 was observed (up to 11%). IN-E8S72 was the only transformation product observed at levels above 10% applied radioactivity in field dissipation studies (maximum 11.7%). All three major transformation products are not expected to accumulate in soil based on field dissipation studies. In the Canadian field trial sites, significant amounts oxathiapiprolin residues in soil carried over to the beginning of the next growing season (20 to 39% of applied radioactivity). A summary of environmental fate data is presented in Table 7, Appendix I, and a summary of major transformation products observed in the environment is presented in Table 8, Appendix I.

In laboratory studies oxathiapiprolin was immobile in soils, and the transformation products IN-RDT31 and IN-RAB06 had low mobility, while IN-E8S72 was very highly mobile. Oxathiapiprolin and its major soil transformation products meet some of the criteria for leaching potential according to Cohen et al. (1984), primarily for persistence in the terrestrial environment, except for IN-E8S72, which also has high mobility (Table 9, Appendix I). Based on a ground water ubiquity score (GUS) of < 1.8, oxathiapiprolin is considered a non-leacher

(Gustafson 1989). In field dissipation studies oxathiapiprolin and its three major transformation products remained mostly in the upper 30 cm of the soil profile and were only sporadically observed to a depth of 70 cm. Based on laboratory mobility studies and observed leaching in field dissipation studies, the leaching potential for oxathiapiprolin and its major transformation products is considered low; however, environmental modelling indicates that combined residues of oxathiapiprolin and its transformation products may eventually reach groundwater, given their persistence in soil.

Oxathiapiprolin can enter the aquatic environment through spray drift and overland runoff from the site of application. In the aquatic environment, oxathiapiprolin partitions from the water to the sediment where it adsorbs strongly to sediment material. Oxathiapiprolin does not hydrolyze and is slightly to moderately persistent in aerobic and anaerobic water and sediment systems. Several major transformation products were identified in laboratory studies (based on total amounts in water and sediment): IN-RYJ52, IN-S2K66, IN-Q7D41, IN-QFD61, IN-S2K67, IN-RSE01, 2-6 DFBA and IN-P3X26. The latter IN-P3X26 is formed only in the presence of sunlight; however phototransformation is not an important route of dissipation. Environmental toxicity data for the aquatic transformation products indicate they are not of concern.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse ecological effects. This integration is achieved by comparing exposure concentrations (i.e., the expected environmental concentration (EEC)) with concentrations at which adverse effects occur (for example, toxicity endpoints such as LC_{50}, LD_{50}, NOEC or NOEL). For characterizing acute risk, acute toxicity values (for example, LC_{50}, LD_{50}, and EC_{50}) are divided by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (e.g., community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (*for example*, 10 for fish, 2 for aquatic invertebrates). The difference in value of the uncertainty factors reflects, in part, the ability of certain organisms at a certain trophic level (i.e., feeding position in a food chain) to withstand, or recover from, a stressor at the level of the population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC = 1 for most species, 0.4 for pollinators and 2 for beneficial arthropods (acute screening tests for predatory mite and parasitoid wasp)). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

The environmental risk of oxathiapiprolin and its related end-use products to non-target organisms was assessed based upon the maximum annual application rate of 560 g a.i./ha for soil applications to field vegetables in Crop Groups 8 and 9, or foliar application to ginseng (for example, 2 × 280 g a.i./ha, with a 7-day interval). All other foliar crops have a maximum seasonal rate of 140 g a.i./ha (i.e., 4 × 35 g a.i./ha, with a 5-day interval), applied by field sprayer with a minimum spray quality of ASAE fine.

A summary of EEC values used for the screening level risk assessment is presented in Tables 11, 12 and 13, Appendix I. Where required, refined EECs are presented in Appendix I for relevant species (i.e., Table 17 for foliar-dwelling organisms, and Tables 24 and 25 for amphibians).

4.2.1 Risks to Terrestrial Organisms

A risk assessment of oxathiapiprolin and its end-use product- formulations oxathiapiprolin 100 g/L OD (for example, Dupont Zorvec Epicaltrin Fungicide and Orondis Fungicide) and Oxathiapiprolin 200 g/L SC (for example, Dupont Zorvec Epicaltrin and OXTP 200SC Fungicide) was undertaken for terrestrial organisms based on available toxicity data. A summary of terrestrial toxicity data is presented in Table 13, Appendix I. Results of the accompanying risk assessment are presented in Tables 16 to 24, Appendix I.

At the screening level, EECs for direct on-field application were considered for soil dwelling organisms, birds, mammals and terrestrial vascular plants. During a refined risk assessment for foliar dwelling arthropods, off-field EECs resulting from spray drift were considered (for example, 11% drift for field sprayers using an ASAE Fine spray quality).

Earthworms and soil dwelling arthropods

Earthworms: To assess the toxicity to earthworms (*Eisenia fetida*), acute and chronic laboratory studies were conducted. Significant mortality was not observed in the acute laboratory studies with oxathiapiprolin, oxathiapiprolin 100 g/L OD, oxathiapiprolin 200 g/L-SC and the transformation products IN-E8S72, IN-QPS10, IN-RAB06, IN-RDT31. The corresponding LC_{50} values were all greater than the highest test concentrations (for example, >100 to >1000 mg a.i. /kg soil dry weight (dw), depending on test substance). On a chronic basis, no significant effects on juvenile growth and survival were observed. The NOEC value for oxathiapiprolin was 1000 mg a.i./kg soil dw and the NOEC values for the transformation products were all 100 mg a.i./kg soil dw.

All acute and chronic screening level risk quotients for earthworms were below the level of concern for oxathiapiprolin and its soil transformation products.

Soil-dwelling arthropods: To assess the toxicity to soil-dwelling arthropods (represented by a soil mite (*Hypoaspis aculeifer*) and a springtail (*Folsomia candida*)), chronic laboratory studies were conducted with oxathiapiprolin, oxathiapiprolin 100 g/L OD, and the transformation products IN-E8S72, IN-QPS10, IN-RAB06, IN-RDT31. For soil mites, significant reductions in reproduction occurred from exposure to IN-QPS10 and IN-RAB06 (NOEC = 50 and 25 mg a.i./kg soil dw, respectively). For springtails, adverse effects on adult mortality and reproduction were observed for oxathiapiprolin and oxathiapiprolin 100 g/L OD (NOEC = 25 mg a.i. /kg soil dw for both).

The levels where toxic effects were observed exceeded the maximum proposed application rates and as a result, all chronic screening level risk quotients for soil-dwelling arthropods were below the level of concern for oxathiapiprolin and its soil transformation products.

Beneficial foliage-dwelling arthropods

To assess the toxicity on foliar-dwelling arthropods, acute and extended laboratory studies and field studies were conducted with oxathiapiprolin 100 g/L OD.

Screening level: The screening level risk assessment for foliar-dwelling organisms exposed to oxathiapiprolin considers the acute toxicity obtained from laboratory experiments using glass plates. Three species were exposed the oxathiapiprolin 100 g/L OD formulation: parasitoid wasp (*Aphidius rhopalosiphi*), predatory mite (*Typhlodromus pyri*) and green lacewing (*Chrysoperlea carnea*). The 48-hour acute LR_{50} for parasitoid wasp was 114 g a.i./ha and the 14-day acute LR_{50} for the predatory mite and green lacewing were >200 g a.i./ha.

At the highest foliar application rate of 2 × 280 g a.i./ha per season for ginseng crops, the screening level risk quotients marginally exceeded the level of concern of 2.0 for all three species (RQ values ranged from < 2.26 to 3.96).

When considering the off-field scenarios (Table 16, Appendix I), the EEC was adjusted for deposition 1 m downwind for an ASAE fine field spray (11% deposition). The resulting risk quotient values for all indicator species were below the level of concern, indicating a negligible risk for beneficial arthropods off-field.

Tier I refined risk characterization: The tier I refinement for parasitoid wasps considers the toxicity endpoints LR_{50} or ER_{50} of >200 g a.i./ha, obtained from a 48-hour extended test with *A. rhopalosiphi* exposed to residues on plant leaf surfaces. Using the same in-field and off-field EECs, risk quotient values are calculated (Table 17, Appendix I). The refined level of concern of 1.0 is still exceeded for on-field exposure; however, as an LR_{50} or ER_{50} was not reached up to 200 g a.i./ha, there is uncertainty as to whether effects are likely to be seen for foliar application to crops at 2 × 280 g a.i./ha (i.e., ginseng). As there was no mortality or plant avoidance or significant reductions in parasitization efficiency ($\alpha = 0.05\%$) seen in wasps up to 200 g a.i./ha, the risks to beneficial arthropods on-field in are expected to be negligible for all other proposed foliar uses (with a maximum seasonal rate of 140 g a.i./ha).

Tier II refinement: Exposure was further characterized with the use of in-field plant interception factors for ginseng, which is the only crop with a foliar application above 140 g a.i./ha. Applying foliar deposition fractions (F_{int}) for beans (a representative leafy crop) that range from 0.25 – 0.80 depending on crop stage, would result in in-field EECs ranging from 113 – 362 g a.i./ha. Corresponding RQs would range from <0.57 to <1.81, indicating a minimal potential for risk to in-field foliar-dwelling arthropods.

Additional data from three field studies conducted on predatory mites in European vineyards showed no significant reduction in predatory mite populations greater than 50% compared to controls at cumulative seasonal rates up to 180 g a.i./ha when exposed to oxathiapiprolin 100 g/L OD formulation. The maximum population reduction observed was 20.4% at six days after the second application (Table 18, Appendix I), with evidence of some recovery in populations by study termination (11.3% population reduction by 28 days after the third application). This rate is greater than the maximum foliar application rate for all crop uses except for ginseng. Therefore, the use of oxathiapiprolin is not expected to pose a risk to beneficial arthropods in crops at rates of up to 180 g a.i./ha. There is however, uncertainly in the amount of risk to foliar-dwelling arthropods at rates up to 560 g a.i, as extended laboratory tests and field studies were conducted at rates up to 200 g a.i./ha only. Therefore, a hazard statement for beneficial arthropods will be required for product labels with foliar application rates greater than 200 g a.i./ha (for example, foliar ginseng use at 2 × 280 g a.i./ha).

Honeybees

Toxicity data for acute oral and contact exposure to adult bees was available for oxathiapiprolin, the formulated end-use product formulations for oxathiapiprolin 100 g/L OD, oxathiapiprolin 200 g/L SC and the transformation products IN-E8S72 and IN-WR791. IN-WR791 is a plant metabolite and IN-E8S72 is closely related to another plant metabolite IN-SKS67, a glucose conjugate of IN-E8S72 that rapidly converts to IN-E8S72. The risk to adult bees was determined for exposure to the technical active ingredient. The endpoints for the two end-use products were equal to, or greater than for the technical active ingredient (Table 13, Appendix I). Additional data from semi-field exposure of honeybees to oxathiapiprolin 100 g/L OD was also considered. The risk assessment did not include an assessment of the oxathiapiprolin transformation products IN-E8S72 and IN-WR791 because the oral and contact LD_{50}'s were all > 100 µg a.i./bee with the exception of IN-WR791 (oral LD_{50} > 56.2 µg a.i./bee) which would classify them as relatively non-toxic according to the classification scheme of Atkins et al. 1981. All endpoints available for risk assessments are summarised in Table 13, Appendix I.

Tier I studies:

Contact exposure (foliar applications): Honeybees can be exposed to oxathiapiprolin from direct application or contact with treated plant material. In order to compare the application rate to the acute contact toxicity endpoint derived in laboratory studies (µg a.i./bee), a conversion from kg a.i./ha to µg a.i./bee is required. The proposed upper-bound residue value for estimating exposure to honeybees is based on the maximum residue value reported by Koch and Weisser 1997 (2.4 µg a.i./bee per 1 kg a.i./ha). The estimated residues per bee following a single application of 280 g a.i./ha is 0.67 µg a.i./bee. A risk quotient (RQ) was calculated by dividing this value by the 72-h contact LD_{50} value of >100 µg a.i./bee for the technical active ingredient. The Level of Concern (LOC) for the Tier 1 acute exposure is 0.4. The calculated RQ is <0.01 (Table 19, Appendix I) which does not exceed the LOC of 0.4, therefore foraging worker bees are not expected to be at risk from direct contact exposure of oxathiapiprolin residues following single foliar applications at 280 g a.i./ha.

Oral exposure (foliar applications): The acute oral exposure estimate for adult bees is calculated by multiplying the single application rate (280 g a.i./ha) by 29 µg a.i./bee per kg a.i./ha. This conversion is based on nectar consumption rates for forager bees (0.292 g/day) primarily derived from Rortais et al (2005) and Crailsheim et al (1992 and 1993) and concentrations in pollen and nectar (98 µg a.i./g) estimated from the T-Rex model. Following the conversion, the estimated oral exposure is 8.01 µg a.i./bee based on the single application rate. The acute risk quotient (RQ) is calculated by dividing this value by the 48-h oral LD_{50} value of >40.26 µg a.i./bee for the technical. The calculated acute RQ is <0.20 (Table 19, Appendix I) which does not exceed the LOC of 0.4,; therefore, oxathiapiprolin in nectar and pollen following foliar applications is not expected to pose a risk to foraging adult bees.

Oral exposure (soil applications): For soil treatments, bees will be exposed via dietary consumption of pollen and nectar that are contaminated as a result of systemic transport of pesticides from soil. For these application types, it is assumed that honeybees will not be directly exposed through contact. The method for estimating dietary exposures to bees resulting from soil treatments is based on an empirically based model developed by Briggs et al. 1982 and 1983, with modifications (referred to as "the Briggs' Model"). This model relates the Log Kow of a chemical to its concentration in plant shoots, which can be used as a surrogate for concentrations in nectar and in pollen. The concentration in nectar and pollen estimated by the Briggs model following a soil application at 280 g a.i./ha and using a Log Kow of 3.6 and the mean Koc value of 8790 mL/g for a number of soils is 0.021 µg a.i./g. The estimated concentration in pollen and nectar may be converted to a dietary-based exposure for adult worker bees using the consumption rates for nectar (0.292 g/day). The calculated acute oral-based exposure for adult bees is therefore 0.006 µg a.i./bee. An acute risk quotient (RQ) is calculated by dividing this value by the 48-h oral LD_{50} value of >40.26 µg a.i./bee for the technical. The calculated RQ is <0.01 (Table 19, Appendix I) which does not exceed the LOC of 0.4; therefore, foraging worker bees are not expected to be at acute risk following soil applications at 280 g a.i./ha.

Semi-field Tunnel Studies

Semi-field studies shift the focus from exposure and effects on individual bees to that of the intact colony. Compared to laboratory studies where exposure is to individual organisms and typically through a single route (for example, contact or oral), semi-field studies can provide clearer lines of evidence for linking multiple routes of exposure to adverse ecological effects. Semi-field studies are also useful for determining the extent to which effects on individual bees identified in Tier 1 laboratory studies are expressed at the colony level. As a larval/brood development study was not submitted for oxathiapiprolin, the results of one semi-field study that was provided (PMRA document number 2364661) were further evaluated.

The effects of Oxathiapiprolin formulation DPX-QGU42 100 g/L OD were tested on the honeybee (*Apis mellifera* L.) under semi-field conditions following the OECD guidance document No. 75 (2007). The guideline was developed to determine the likelihood of adverse effects of a chemical on bee brood development. The formulation was applied three times at rates of 60 (T1), 120 (T2), and 180 g a.i./ha (T3) to field of test plants (*Phacelia tanacetifolia*). The third application was conducted when plants were flowering at day time and when bees were foraging. Honeybee (*Apis mellifera*) hives were exposed to treated plants for 7 days in the tunnel, and then monitored for additional 18 days at another site that was approximately 7 km away from the exposure site. The study included a negative control using tap water and a positive control using fenoxycarb at 150 g a.i./ha that was applied once at the same time when the third application was applied in the treatment groups. There were three replicates for each treatment.

No treatment-related or biologically relevant effects on the number of dead bees of all ages, flight activity, hive strength were observed in the treatment at 3x120 g a.i./ha and less (T1 and T2). The treatment of 3x180 g a.i./ha (T3) did not show any treatment-related effects on honeybees at the colony level at the end of study based on the hive strength and total number of brood. It was noted that the study also did not detect the effects at the colony level for the reference chemical, fenoxycarb at 150 g a.i./ha. However, potentially slight effects of the application three times per treatment at a rate of 180 g a.i./ha (Treatment 3) on the mortality of pupae and young honeybees at the individual level may not be excluded.

In the study, slight but statistically higher numbers of total dead pupae and young bees were found in the treatment with the test chemical at 3x180 g a.i./ha (T3) during the whole post-application period after the application during flowering (DAA0-25). The mean number of dead pupae, dead young bees and dead malformed pupae and adult bees during this period was 7.0, 7.3, 6.7, 15.7 and 69.7 bees per hive in the Control, T1, T2, T3 and fenoxycarb reference (R) treatments respectively. The differences were statistically significant for the T3 and R treatments ($p \leq 0.05$; Dunnett's one-sided t-test). However, mortality in T3 was low and was within the range of variation observed during the hive acclimatization period in the test tunnel (DAA-5 to 0). When comparing the mortality during the first 7 days post application (DAA0-7) in T3 to the rest of the observation period (DAA8-25), the majority of mortalities occurred within the first week post application; mortalities in T3 during DAA8 -25 were similar to controls, suggesting possible recovery for the young in the hives. In contrast, mortality of the young remained high throughout the entire observation period for the bees exposed to the reference chemical. It was noted that the mortality in the treatment at 3x180 g a.i./ha during DAA0-25 was clearly lower than that in the positive control during the same period of time, indicating the effect of the treatment was not as strong as the reference chemical at the test rate

Using marked brood cells, the study found the mean brood index and the mean brood compensation index were consistently lower in the treatment than in the control, and the mean of brood termination rate was higher in the treatment than in the control at the end of study. However, the differences were slight and not statistically significant, likely because of the large data variation in the study.

Risk Assessment Conclusions

Acute toxicity testing with young adult bees indicates that oxathiapiprolin is practically non-toxic to honeybees on an acute contact exposure basis (LD_{50} value of >100 µg a.i./bee) and on an acute oral exposure basis (LD_{50} value of >40.26 µg a.i./bee). Risk quotients for both were below the LOC of 0.4. The risk from formulated enduse products Oxathiapiprolin 100 g/L OD and Oxathiapiprolin 200 g/L SC to young adult honeybees are not expected to be any greater than for oxathiapiprolin as toxicity endpoints were equal to or greater than that of the technical active ingredient (Table 12, Appendix I).

Oxathiapiprolin does not pose a risk to bees for uses at rates of up to 3 × 120 g a.i./ha (360 g a.i./ha per season based on an available semi-field study where bees were allowed to actively forage on residues following multiple applications of the compound, including one foliar application at full bloom while bees were foraging). Therefore, all proposed foliar application rates at 4 × 35 g a.i./ha (140 g a.i./ha per season) pose a negligible risk to honeybees. Slight effects on the mortality of pupae and young honeybees in the hive were observed at the highest rate of 3 × 180 g a.i. /ha (540 g a.i. /ha per season), which corresponds to the maximum seasonal rate of 560 g a.i. /ha for soil applications to Crop Groups 8 and 9 (fruiting and cucurbit vegetables) and for foliar use on ginseng. These effects were not seen at either of the two lower rates (for example, 3 × 60 g a.i./ha or 3 × 120 g a.i./ha), and there is no indication that the slight increase in pupal/young bee mortality at the high rate resulted in detectable effects to colony development (including colony health, hive strength and total number of brood). In addition, the slight increase in mortality of young bees occurred primarily during the first 7 days post foliar application, with evidence of recovery in the remaining 18 day observation period. Therefore, the use of oxathiapiprolin at rates up to 560 g a.i./ha per season is not expected to pose a risk to honeybee colony health for the following reasons: 1) although statistically higher than controls, the observed mortality of pupae/young bees in the study hives at seasonal rate of 540 g a.i./ha was low, 2) overall colony health, hive strength and number of brood were not significantly affected, 3) crops receiving soil applications only will not have foliar surface residues during flowering, as occurred in the semi-field trial, and 4) ginseng (the only foliar-applied crop at this high rate) is not highly attractive to bees. Therefore, mitigation will not be required on the product labels.

Birds and mammals

Oxathiapiprolin and the formulation product Oxathiapiprolin 100 g/L OD are practically non-toxic to Northern bobwhite quail (*Colinus virginianus*), mallard duck (*Anas platyrhynchos*) and Zebra finch (*Poephila guttata)* on both an acute oral and acute dietary exposure basis (oral LD_{50} values >2250 mg a.i./kg bw and dietary LD_{50} values >1280 mg a.i./kg bw/d). Chronic exposure to oxathiapiprolin resulted in no treatment-related adverse effects on reproductive parameters or on the parental generation for Northern bobwhite quail up to the highest test concentration, with a resulting NOEC of 1200 mg a.i./kg diet (NOEL = 156.3 mg a.i./kg bw/d). For mallard duck, significant reductions in hatchability and subsequent impacts on the number of 14 day old survivors were observed at the highest treatment level. The resulting NOEC was 920 mg a.i./kg diet (NOEL = 117.4 mg a.i./kg bw/d).

Based on the available data, oxathiapiprolin is practically non-toxic to small mammals (rats) on an acute oral basis with the most sensitive LD_{50} of >5000 mg a.i./kg bw. In a rat two-generation reproduction study, the most sensitive effects were decreased body weights and body-weight gains in F2 pups at 1195.6 mg a.i./kg bw/day, resulting in an offspring NOAEL of 411.4 mg a.i./kg/day.

Birds and mammals may be exposed to oxathiapiprolin following the ingestion of plant materials and insects sprayed with oxathiapiprolin during foliar application or ingestion of insects exposed to oxathiapiprolin during soil application. The screening level risk assessment for Oxathiapiprolin 100 g/L OD is conducted for direct on-field exposure at the maximum proposed application rate of 2 × 280 g a.i./ha, assuming exposure occurs entirely through the consumption of food sources contaminated with oxathiapiprolin at the maximum nomogram residue levels, the most conservative scenario.

The screening level risk assessment shows that for the worst case exposure scenario RQs for acute adverse effects and reproductive effects are below the level of concern for all sizes of birds and mammals.

Non-target terrestrial vascular plants

The toxic effects of oxathiapiprolin on vegetative vigour and seedling emergence of terrestrial vascular plants were tested at the maximum nominal application rate of 600 g a.i. /ha using the oxathiapiprolin 100 g/L OD formulation. Inhibition of survival, shoot length and shoot dry weight did not exceed 25% in any of the six dicotyledonous and four monocotyledonous species tested in either the seedling emergence or vegetative vigor studies.

A screening level assessment was conducted for the 100 g/L OD formulation using the on-field EECs based on the maximum application rates of 2 × 280 g a.i./ha and a mean measured ER_{25} of >584 g a.i./ha for seedling emergence and >629 g a.i./ha for vegetative vigour. Screening level risk quotients were below the level of concern for oxathiapiprolin exposure to terrestrial vascular plants for both seedling emergence and vegetative vigour effects.

4.2.2 Risks to Aquatic Organisms

Aquatic organisms can be exposed to oxathiapiprolin as a result of spray drift and runoff. To assess the potential for adverse effects, screening level EECs in the aquatic environment were calculated based on a direct application of 2 × 280 g a.i./ha at a 7 day interval and an aquatic whole-system representative half-life (t_R) of 229 days at 20°C to a 15-cm deep water body representing a seasonal pond suitable for amphibians and an 80-cm deep water body representing a permanent pond. Oxathiapiprolin was assumed to be instantaneously and completely mixed within the water body. The resulting EECs were 0.369 mg a.i./L for a water body of 15 cm in depth and 0.0693 mg a.i./L for a water body of 80 cm in depth (Table 10, Appendix I).

A risk assessment of oxathiapiprolin, the end use product oxathiapiprolin 100 g/L OD and the major and minor oxathiapiprolin transformation products observed in water and soil biotransformation studies was undertaken for freshwater and marine aquatic organisms based on available toxicity data. A summary of aquatic toxicity data for oxathiapiprolin is presented in Table 14, Appendix I. When calculating RQ values, acute toxicity endpoints (E_rC_{50} and LC_{50}) are divided by an uncertainty factor of 2 for aquatic plants and invertebrates and 10 for fish species. No uncertainty factors are applied to chronic NOEC endpoints. The accompanying risk assessment is presented in Tables 23 to 25.

Algae and plants

For freshwater species: Acute toxicity testing with freshwater algae (*Pseudokirchneriella subcapitata*) was performed for oxathiapiprolin, oxathiapiprolin 100 g/L OD and several minor and major transformation products. Toxicity to the blue-green alga *Anabaena flos-aquae* and the diatom *Navicula pelliculosa* was also determined for oxathiapiprolin. Statistically significant ($p < 0.05$) effects on the biomass or growth rate of *P. subcapitata* was observed for oxathiapiprolin 100 g/L OD and several of the aquatic transformation products. For all tests however, the EC_{50} values were determined to be greater than the highest achievable test concentrations, with the exception of the transformation product IN-QPS10. For IN-QPS10, significant reductions in yield > 50% were observed (E_yC_{50} = 0.814 mg/L).

The levels where toxic effects were observed exceeded the maximum proposed application rates and as a result, all screening level risk quotients for oxathiapiprolin and its transformation products were below the level of concern for freshwater algae.

Acute toxicity to aquatic vascular plant duckweed (*Lemna gibba*) was determined for oxathiapiprolin in a static system. No statistically significant ($p < 0.05$) inhibition on the growth rate or biomass of *L. gibba* was observed up to the highest test concentration. The EC_{50} was determined to be > 0.790 mg a.i./L.

The screening level risk quotient for oxathiapiprolin exposure was below the level of concern for freshwater plants.

For estuarine/marine species: Acute toxicity to the saltwater diatom (*Skeletonema costatum*) was determined for oxathiapiprolin in a static system. No significant effects on biomass or growth rate were found up to the highest test concentration (EC_{50} > 0.460 mg a.i./L).

The screening level risk quotient for oxathiapiprolin exposure was below the level of concern for marine algae.

Aquatic invertebrates

For freshwater species: Both acute and chronic tests on aquatic invertebrates, including *Daphnia magna* (water dwelling) and chironomus (sediment dwelling) were performed for oxathiapiprolin, oxathiapiprolin 100 g/L OD and several minor and major transformation products.

Daphnia magna: In the acute toxicity test on *D. magna*, significant mortality/immobility was observed following 48 hours of exposure to oxathiapiprolin at the highest test concentration. The resulting EC_{50} value was 0.629 mg a.i./L. For oxathiapiprolin 100 g/L OD and most transformation products, acute EC_{50} values were greater than the highest achievable test concentrations. For the transformation products IN-QFD61 and IN-QPS10, significant mortality above 50% was observed, with EC_{50} values of 5.14 and 14.7 mg/L, respectively. When *D. magna* was exposed to oxathiapiprolin on a chronic basis, no treatment-related effects on survival, reproduction or growth were observed up to the highest test concentration (NOEC = 0.750 mg a.i./L).

The levels where toxic effects were observed exceeded the maximum proposed application rates and as a result, all acute and chronic screening level risk quotients for *Daphnia magna* were below the level of concern for oxathiapiprolin and its aquatic transformation products.

Chironomus: In the acute toxicity test on larvae of the midge (*Chironomus riparius*), no mortality or sublethal effects were observed following 48 hours of exposure to oxathiapiprolin ($EC_{50} > 0.56$ mg a.i./L). When *C. riparius* was exposed to oxathiapiprolin via spiked sediments in a static water-sediment system on a chronic basis, statistically significant effects on emergence rate and development rate were observed ($p < 0.05$). The NOEC for emergence rate (the most sensitive endpoint) was determined to be 0.17 mg a.i./L based on time-weighted average concentrations in overlying water. When exposed to oxathiapiprolin via spiked water in a static water-sediment system on a chronic basis, statistically significant effects on emergence rate were observed ($p < 0.05$; NOEC = 0.099 mg a.i./L based on time-weighted average concentrations in overlying water). Chronic exposure to the transformation product IN-Q7D41 via spiked water in a static water-sediment system resulted in statistically significant effects on development rate ($p < 0.05$; NOEC = 0.14 mg a.i./L based on time-weighted average concentrations in overlying water).

Acute and chronic screening level risk quotients for exposure of oxathiapiprolin and IN-Q7D41 in overlying water to the sediment-dwelling invertebrate *Chironomus riparius*, were below the level of concern.

For estuarine/marine species: Acute exposure to Eastern oysters (*Crassostrea virginica*) and mysid shrimp (*Americamysis bahia*) did not result in reduction in shell growth (oysters) or mortality (mysids) above 50% of control levels at concentrations up to highest achievable test concentrations of oxathiapiprolin (EC_{50} values >0.330 mg a.i./L and >0.640 mg a.i./L, respectively, based on mean measured concentrations. Chronic exposure to *A. bahia* over its life cycle however, resulted in significant reductions in number of young produced per female ($p < 0.05$; NOEC = 0.058 mg a.i./L based on mean measured concentrations.

The risk to benthic and pelagic marine invertebrates was assessed for oxathiapiprolin exposure to oysters and mysid crustaceans, respectively. Screening level risk quotients for acute exposure to oxathiapiprolin did not exceed the level of concern for marine invertebrates. Chronic exposure to mysids marginally exceeds the level of concern (RQ = 1.19), based on observed reductions in reproduction above this level of exposure. Chronic risk from oxathiapiprolin exposure however, is unlikely in the marine environment given the slight exceedence of the level of concern and the conservative assumption that mysids are exposed on a chronic basis to all oxathiapiprolin entering the water column, given the partitioning properties to sediments and the higher rates of water exchange in estuarine environments. Therefore oxathiapiprolin is not expected to pose a chronic risk to marine invertebrates.

Fish

For freshwater species: Acute toxicity of oxathiapiprolin, oxathiapiprolin 100 g/L OD and several transformation products to fish was determined with for rainbow trout (*Oncorhynchus mykiss*), representing a cold water species, and the acute toxicity of oxathiapiprolin was determined for fathead minnow (*Pimephales promelas*), a warm water species. Chronic toxicity of oxathiapiprolin to fish was determined in an Early-Life-Stage (ELS) test with rainbow trout.

Following 96 hours of exposure to oxathiapiprolin or oxathiapiprolin 100 g/L OD, there were no mortalities observed at any test concentration for both fish species. In all cases, the acute LC_{50} was greater than the highest achievable mean-measured concentrations. For rainbow trout exposed to oxathiapiprolin 100 g/L OD, fish were lethargic at the two highest concentrations for the first 48 hours, but all fish appeared normal after 72 - 96 hours. Of the transformation products tested, only IN-QPS10 had significant mortality (LC_{50} = 6.96 mg/L), but otherwise no transformation products exhibited mortality or sublethal effects up to the highest concentrations tested.

In the chronic ELS test with fathead minnow, no biologically significant effects were observed on hatchability, time to hatch or larval survival. However, there was a statistically significant decrease in growth (length and weight) on Day 60 post-hatch, which occurred at the highest test concentration ($p < 0.05$). The NOEC was determined to be 0.46 mg a.i./L. In addition, no statistically significant morphological and behavioural effects were observed.

Screening level acute and chronic risk quotients for both species of fish were below the level of concern. The acute risk quotient for rainbow trout from exposure of the end use product oxathiapiprolin 100 g/L OD formulation of <1.36 may slightly exceed the level of concern based on an LC_{50} value above the highest achievable test concentration for oxathiapiprolin. However, the end use product is not expected to pose an acute risk to rainbow trout given the lack of mortality in the study up to the highest test concentration and the lack of toxicity to rainbow trout and bluegill sunfish from the technical active ingredient.

The acute risk of major and minor oxathiapiprolin transformation products observed in water and soil biotransformation studies were also assessed for rainbow trout. Of the transformation products assessed, only IN-Q7D41 showed a potential risk based on an LC_{50} endpoint greater than the highest achievable test concentration (i.e., RQ <3.83). The screening level EEC for IN-Q7D41 is based on the overly conservative assumption that all available oxathiapiprolin in the water converted directly to IN-Q7D41. However, in the laboratory aerobic aquatic degradation study (PMRA document number 2564772), the maximum amount of IN-Q7D41 formed in the water column was ≤1.5% of applied oxathiapiprolin. Based on this level of exposure, the revised risk quotient for IN-Q7D41 of < 0.1 is below the level of concern. Therefore, oxathiapiprolin transformation products are not expected to pose a risk to freshwater fish.

For estuarine/marine species: Acute and chronic toxicity of oxathiapiprolin to marine/estuarine fish was determined with saltwater sheepshead minnow (*Cyprinodon variegatus*). The acute test on sheepshead minnows showed that oxathiapiprolin did not cause mortality or sublethal behavioural effects following 96 hours of exposure. The LC_{50} was >0.65 mg a.i./L, the highest concentration tested. In the chronic ELS study with sheepshead minnow, there were no treatment-related effects indicated at any level on hatching success, time to hatch, post-hatch survival, wet weight, or length. In addition, there were no treatment-related clinical signs of toxicity. There was however, a significant reduction in growth based on fish dry weight ($p < 0.05$, NOEC = 0.23 mg a.i./L).

The acute risk quotient for sheepshead minnow was < 1.07 in an 80-cm deep marine water body based on an LC_{50} value > 0.65 mg a.i./L. Given that no mortality was observed in the sheepshead minnow up to 0.65 mg a.i./L, oxathiapiprolin is not expected to pose an acute risk to marine fish. In addition, the level of concern was not exceeded for marine fish from chronic exposure oxathiapiprolin. Therefore, marine fish are not expected to be at risk from oxathiapiprolin up to the highest use rate of 560 g a.i./ha per season.

Amphibians

The risk to amphibians was determined using acute and chronic toxicity data for rainbow trout as a surrogate species. The risk quotient for acute exposure for amphibians in 15 cm water was <5.55, however, there is uncertainty as to whether the level of concern was exceeded as there was no mortality for rainbow trout up to 0.69 mg a.i./L and the LC_{50} was therefore > 0.69 mg a.i./L. Oxathiapiprolin is not expected to pose a risk to amphibians on a chronic basis as the level of concern was not exceeded using the chronic fish ELS endpoint as a surrogate for amphibians in 15 cm water (RQ = 0.8).

Tier I refinement: The potential for acute risk to amphibians was refined by assessing the risk for foliar applications at the lower rate of 180 g a.i./ha per season, and by further characterizing low and high-rate EECs for adjacent off-field aquatic habitats based on input from spray drift. A separate assessment for runoff was not conducted given the slight exceedance of the level of concern based on an acute toxicity endpoint for rainbow trout that did not result in any mortality or sublethal toxicity up to the achievable solubility limit in the study and due to the lack of chronic risk to amphibians.

Estimated environmental concentrations for the lower foliar application rate of 180 g a.i./ha per season were also determined for amphibian habitats to determine if the level of concern was exceeded for all other foliar applications except ginseng (Table 25, Appendix I). The resulting RQ of < 1.3 for amphibians exposed to oxathiapiprolin at the lower application rate of 180 g a.i./ha may still marginally exceed the level of concern, although there is uncertainty as the endpoint is based on no effects up the highest test concentration.

Refined EEC's for spray drift considered field sprayer applications at both the low rate for foliar use on all field crops except ginseng at rates up to 140 g a.i./ha per season, and for ginseng at rates up to 560 g a.i./ha per season, taking into account an 11% drift deposition factor for ASAE fine field sprayer applications to water bodies 1 m downwind of the site of application (Table 28, Appendix I).

Refined risk quotients for acute exposure of oxathiapiprolin spray drift do not exceed the level of concern for amphibians for foliar applications up to 560 g a.i./ha.

4.2.3 Environmental Incident Reports

No incident reports were available. This is a new active ingredient and incident reports are not expected.

5.0 Value

5.1 Consideration of Benefits

Diseases caused by oomycete fungi can infect all plant parts, including the marketable parts. A decrease in the quality of fruit can have a significant impact on revenue. Some commodities have very low tolerance for damage, which can result in unmarketable fruit or significantly downgrade its value. The economic benefit of oxathiapiprolin was confirmed in multiple efficacy trials by significantly increasing the yield and/or quality of major commodities grown in Canada.

Oxathiapiprolin is compatible with current integrated pest management (IPM) practices and introduces a new mode of action that is effective against oomycetes. In addition, registration of these fungicide products will allow growers access to products that will address several priority diseases in Canada.

Resistance development has been a problem in certain diseases caused by oomycetes, such as cucumber downy mildew. For phytophthora diseases, oxathiapiprolin used as a soil drench will reduce soil inoculum, which provides early protection that can delay infection and reduce the severity of an epidemic. Alternative fungicides with different modes of action are registered for the control or suppression of the proposed diseases on most of the proposed crops. For those crops with limited alternatives, a new mode of action fungicide may extend disease control when introduced to a spray program as a rotational product. The addition of oxathiapiprolin to a disease management plan for all of the proposed crops also provides a rotational product to help delay of the development of resistance. Please refer to Appendix I, Table 26, for more information on alternative products.

Oxathiapiprolin has a unique mode of action that is currently classified by the Fungicide Resistance Action Committee (FRAC) as a group U15 fungicide. Although FRAC has not yet issued resistance management use recommendations for this active ingredient, the registrant has provided their own recommendations in order to maintain the sustainability of oxathiapiprolin. Recommendations include a maximum of two sequential applications before rotating to a different mode of action and limiting the number of seasonal applications to 1/3 of the total foliar or soil applications.

5.2 Effectiveness Against Pests – Dupont Zorvec Enicade Fungicide

Dupont Zorvec Enicade Fungicide is the oil dispersion (OD) formulation of oxathiapiprolin.

5.2.1 Downy mildew (*Peronospora* spp., *Pseudoperonospora cubensis*, *Bremia lactucae*)

Blue mould (*Peronospora tabacina*)

Control of downy mildew was proposed for Crop Group 3 (Bulb Vegetables), Crop Group 4 (Leafy Vegetables), Crop Group 5A (Head and Stem Brassica Vegetables), Crop Group 9 (Cucurbit Vegetables), and succulent pea. Blue mould on tobacco is caused by a related pathogen and so is included in this summary. Oxathiapiprolin is to be applied to foliage at rates between 8.75 and 35 g a.i./ha. Twenty efficacy trials conducted between 2009 and 2012 and a scientific rationale were submitted to support the claims.

Oxathiapiprolin demonstrated commercially acceptable levels of control against multiple downy mildew pathogens affecting the labelled crops. The claims were extrapolated to other crops affected by the tested pathogens and to greenhouse tomato, pepper and cucumber. Data generated on onion, spinach, cucurbit crops and tobacco was extrapolated to support a related pathogen affecting succulent pea. The reviewed value information was sufficient to support the claims of control of downy mildew on the indicated crops at the proposed rates and timing.

5.2.2 Diseases incited by *Phytophthora* spp.

Phytophthora spp. are aggressive pathogens that incite foliar, crown, and root diseases on many crops. Claims of control of phytophthora blight, late blight and/or root rot were proposed for Crop Group 9 (Cucurbit Vegetables), potato, tomato, pepper, eggplant and ginseng. Oxathiapiprolin is to be applied to foliage at rates between 8.75 and 35 g a.i./ha except for ginseng (70 – 280 g a.i./ha) or as a soil drench at rates of 70 – 280 g a.i./ha. A total of 21 efficacy trials conducted between 2009 and 2011 were submitted to support the claims; nine trials were submitted on phytophthora blight, 10 trials were submitted on late blight, and two trials were submitted on root rot. Foliar, drench and chemigation (via drip irrigation) application methods were tested in the trials.

Commercially acceptable control was demonstrated in the trials against the labelled diseases using the tested application methods. The claims were extrapolated to other crops affected by the tested pathogens and to greenhouse tomato, pepper and cucumber. The reviewed value information was sufficient to support the claims of control of phytophthora blight on Crop Group; 9 tomato, pepper, and eggplant; control of late blight on potato, tomato, pepper and eggplant, and control of foliar blight and root rot on ginseng. The use patterns were supported at the proposed rates and timings.

5.2.3 Comparison of OD and SC formulations, Extrapolation to Dupont Zorvec Epicaltrin Fungicide

Dupont Zorvec Epicaltrin Fungicide is the suspension concentrate (SC) formulation of oxathiapiprolin. Dupont Zorvec Epicaltrin Fungicide is intended as a soil-applied product to control the soil phase of phytophthora blight on Cucurbit Vegetables, tomato, pepper and eggplant.

Bridging trials were conducted to demonstrate comparable efficacy between the OD (oil dispersion) and SC formulations. Five trials conducted on cucurbit crops, tomato and pepper tested the two formulations as side-by-side treatments using foliar and chemigation via drip irrigation application methods. Comparable efficacy was observed in all trials; therefore, the two formulations are considered biologically equivalent. As such, the uses proposed for the Epicaltrin Fungicide label were extrapolated from data reviewed in support of Dupont Enicade Fungicide.

5.2.4 Extrapolation to Orondis Fungicide and OXTP 200SC Fungicide

Orondis Fungicide and OXTP 200SC Fungicide are biologically equivalent to Dupont Zorvec Enicade Fungicide and Dupont Zorvec Epicaltrin Fungicide respectively. All uses supported for Dupont Zorvec Enicade Fungicide and Dupont Zorvec Epicaltrin Fungicide were extrapolated to Orondis Fungicide and OXTP 200SC Fungicide respectively.

5.2.5 Additional application methods

The submitted information demonstrated the value of treatment of crops with oxathiapiprolin to control downy mildew and phytophthora diseases on multiple crops using foliar application, soil drench application and chemigation through drip irrigation equipment. Other application methods proposed include in-furrow treatments or application via transplant water (injected into planting hole when transplanting). A comparison of the solution rates and application methods to the tested methods revealed comparable application rates between all techniques. Based on the value of the application methods and the prescriptive application directions ensuring proper application rates, in-furrow application and application via transplant water were supported.

5.3 Non-Safety Adverse Effects

No phytotoxic effects were observed in any trial as a result of treatment with either formulation of oxathiapiprolin.

5.4 Supported Uses

All of the proposed use claims were supported for registration by the submitted value information. Certain crop groups were amended based on the potential of certain crops to be grown commercially in Canada or their susceptibility to the disease and pathogen. The interval for one crop group was amended to reflect the use pattern tested in efficacy trials. See Table 27, Appendix I, for a summary of the supported uses.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, for example, persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, oxathiapiprolin and its major transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Oxathiapiprolin does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Table 25, Appendix I for comparison with Track 1 criteria.
- Transformation products of oxathiapiprolin do not meet all Track 1 criteria based on log K_{ow} values below the Track 1 criterion for bioaccumulation. See Table 25, Appendix I for comparison with Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

[6] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

- Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances and allergens known to cause anaphylactic-type reactions, are not expected to be present in the technical product oxathiapiprolin;
- Based on the formulating processes used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances and allergens known to cause anaphylactic-type reactions, are not expected to be present in the formulation products DuPont Enicade Fungicide, Orondis Fungicide, or DuPont Zorvec Fungicide, OXTP 200SC Fungicide;
- The end-use product DuPont Enicade Fungicide, Orondis Fungicide, contains aromatic petroleum distillates which are toxic to aquatic organisms. An aromatic petroleum distillates hazard statement will be required on the end-use product label.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for oxathiapiprolin is adequate to define the majority of toxic effects that may result from exposure. Apart from offspring effects at the limit dose of testing in the rat 2-generation reproductive toxicity study, there were no significant toxicological effects in the database. There was no evidence of increased susceptibility of the young in the toxicity studies submitted. There was no evidence of carcinogenicity in mice or rats following longer-term dosing. The risk assessment protects against the toxic effects noted by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Mixers, loaders and applicators handling DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide and workers re-entering treated fields and greenhouses are not expected to be exposed to levels of oxathiapiprolin that will result in health risks of concern when DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, or OXTP 200SC Fungicide are used according to label directions. The personal protective equipment on the product labels is adequate to protect workers while applying DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide,

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[7] NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

[8] DIR2006-02, *PMRA Formulants Policy*.

Orondis Fungicide, and OXTP 200SC Fungicide using backpack, manually-pressurized handwand or mechanically-pressurized handgun to greenhouse cucumbers, tomatoes, and peppers or when applying to bulb vegetables, brassica leafy vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, ginseng, tobacco, succulent peas, and potatoes using groundboom, in-furrow or with chemigation.

Bystander exposure is not expected to result in health risks of concern when DuPont Zorvec Enicade Fungicide, DuPont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide are used according to label directions.

The nature of the residues in plants and animals is adequately understood. The residue definition for enforcement is oxathiapiprolin in plant products and in animal matrices. The proposed use of oxathiapiprolin on potatoes, bulb vegetables, leafy vegetables, head and stem *Brassica* vegetables, tomato, pepper, eggplant, cucurbit vegetables, ginseng and succulent peas does not constitute a risk of concern for chronic dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend MRLs. The PMRA recommends that the following MRLs be specified for residues of oxathiapiprolin.

Commodity	Recommended MRL (ppm)
Leafy Greens (Crop Subgroup 4-13A)	15
Dried tomatoes	3.0
Green Onion (Crop Subgroup 3-07B)	2.0
Brassica Head and Stem Vegetables (Crop Group 5-13)	1.5
Edible-podded dwarf peas	1.0
Edible-podded peas	1.0
Edible-podded snow peas	1.0
Edible-podded sugar snap peas	1.0
Fruiting Vegetables (Crop Group 8-09)	0.5
Cucurbit Vegetables (Crop Group 9)	0.2
Ginseng roots	0.15
Succulent shelled English peas	0.05
Succulent shelled garden peas	0.05
Succulent shelled green peas	0.05
Succulent shelled peas	0.05
Bulb Onion (Crop Subgroup 3-07A)	0.04
Tuberous and Corm Vegetables (Crop Subgroup 1C)	0.01
Milk, fat, meat and meat byproducts of cattle, goats, horses, hogs and sheep	0.01

7.2 Environmental Risk

Oxathiapiprolin is moderately persistent to persistent in the terrestrial environment and moderately persistent in the aquatic environment. Oxathiapiprolin residues in soil may carry over to the following growing season. Oxathiapiprolin is relatively immobile in soil and has a limited potential to leach to groundwater. It may enter aquatic environments through spray drift or surface runoff. In aquatic environments, oxathiapiprolin will move from the water to the sediments. Oxathiapiprolin may pose a risk to non-target amphibians at the proposed use rates. When applied as a foliar spray at 560 g a.i./ha it may also pose a risk to beneficial arthropods living within the treated field. Foliar applications of oxathiapiprolin at the lower rate of 140 g a.i./ha per season are not expected to pose a risk to non-target terrestrial organisms. The identified risks can be mitigated with spray buffer zones to protect sensitive amphibian habitats from spray drift and through the use of label statements to inform and instruct users regarding potential risks to aquatic organisms, beneficial arthropods, and to the environment.

7.3 Value

The value information submitted to register four end-use products containing oxathiapiprolin were sufficient to demonstrate their value in pest management for various crops. Oxathiapiprolin is a new mode of action fungicide effective against oomycete pathogens. The registration of oxathiapiprolin products addresses several disease priorities identified by growers. These new products may be integrated into an IPM program with cultural methods and other fungicides to control important diseases and contribute to agricultural sustainability through resistance management.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of DuPont Zorvec Technical Fungicide, Dupont Zorvec Enicade Fungicide, Dupont Zorvec Epicaltrin Fungicide, Orondis Fungicide, and OXTP 200SC Fungicide, containing the technical grade active ingredient oxathiapiprolin, for use against selective oomycete diseases on bulb vegetables, brassica (cole) leafy vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, ginseng, tobacco, peas, and potatoes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

♂	male
♀	female
µg	micrograms
°C	degrees Celsius
a.i.	active ingredient
a.s.	active substance
AD	administered dose
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
atm	atmosphere
BBCH	Biologishe Bundesanstalt, Bundessortenamt and Chemical industry
BCF	bioconcentration factor
bw	body weight
BW	generic body weight
bwg	body-weight gain
CAS	Chemical Abstracts Service
CAF	composite assessment factor
CDC	Center for Disease Controls and Prevention
cm	centimetres
d	day
DAT	days after treatment
DALA	days after last application
DEEM-FCID	Dietary Exposure Evaluation Model – Food Commodity Intake Database
DFA	difluroacetic acid
DFOP	double first-order in parallel
DT$_{50}$	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT$_{90}$	dissipation time 90% (the dose required to observe a 75% decline in concentration)
dw	dry weight
EC25	effective concentration on 25% of the population
EC$_{50}$	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental concentration
ELISA	enzyme-linked immunosorbent assay
ELS	Early-Life-Stage
EP	end-use product
ER$_{25}$	effective rate for 25% of the population
ER50	effective rate on 50% of the population
ErC50	effective concentration on 50% of the population, based on growth rate
EyC50	effective concentration on 50% of the population, based on biomass yield
F1	first generation

F2	second generation
FDA	*Food and Drugs Act*
FIFRA	United States *Federal Insecticide, Fungicide, and Rodenticide Act*
F_{int}	foliar deposition fractions
FIR	food ingestion rate
FOB	functional observational battery
FRAC	Fungicide Resistance Action Committee
FS	flowable suspension formulation
g	gram
GAP	good agricultural practice
GI	gastrointestinal
GLP	good laboratory practices
GUS	groundwater ubiquity score
h	hour
ha	hectare
HAFT	highest average field trial
HDPE	high-density polyethylene
Hg	mercury
HPLC	high performance liquid chromatography
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
ILV	independent laboratory validation
IPM	Integrated Pest Management
IORE	indeterminate order rate equation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_d	soil-water partition coefficient
Kdes	soil-water desorption coefficient
Kdesoc	soil-water desorption coefficient adjusted according to organic carbon content
Kdoc	soil-water partition coefficient adjusted according to organic carbon content
K_F	Freundlich adsorption coefficient
$K_{F\text{-}OC}$	Freundlich adsorption quotient normalized to organic carbon
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
LC	liquid chromatography
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
IOBC	International Organisation for Biological Control
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOEAER	lowest observed ecologically adverse effect rate
LOEC	low observed effect concentration
LOQ	limit of quantitation

LR_{50}	lethal rate 50%
m	metre
mg	milligram
mL	millilitre
MAS	maximum average score
MoA	mode of action
MOE	margin of exposure
mPa	milliPascals
MRL	maximum residue limit
MRM	multiresidue method
MS	mass spectrometry
MS/MS	tandem mass spectrometry
m/z	mass-to-charge ratio for an ion
na	not analysed
N/A	not applicable
NAFTA	North American Free Trade Agreement
NCHS	National Center for Health Statistics
NHANES/WWEIA	National Health and Nutritional Examination Survey, What We Eat in America
nm	nanometre
NMR	nuclear magnetic resonance
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEAER	no observed ecologically adverse effect rate
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
NR	not reported
NZW	New Zealand white rabbit
OC	organic carbon content
OCSPP	Office of Chemical Safety and Pollution Prevention
OD	oil dispersion
OECD	Organisation for Economic Co-operation
OM	organic matter content
Pa	Pascals
PAI	pure active ingredient
PBI	plantback interval
PCPA	*Pest Control Product Act*
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PND	post-natal day
ppb	parts per billion
ppm	parts per million
RAC	raw agricultural commodity

RD	residue definition
RQ	risk quotient
SC	suspension concentrate
SFO	single first-order kinetic model
STMR	supervised trial mean residue
STMdR	supervised trial median residue
$t_{1/2}$	half-life
TGAI	technical grade active ingredient
TP	transformation products
t_R	representative half-life
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
US	United States of America
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
wt	weight

Appendix I Tables and Figures

Table 1 Toxicity Profile of Oxathiapiprolin End-Use Products

Study Type/ Animal/ PMRA Document Number	Study Results
Acute Toxicity Studies – Orondis Fungicide and Dupont Zorvec Enicade	
Acute Oral Toxicity (gavage) Sprague Dawley rats PMRA 2365064	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute Dermal Toxicity Sprague Dawley rats PMRA 2365066	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute Inhalation Toxicity Sprague Dawley rats PMRA 2365069	LC_{50} > 5.08 mg/L **Low toxicity**
Eye Irritation NZW rabbits PMRA 2365079	MAS = 0/110 **Non irritating**
Dermal Irritation NZW rabbits PMRA 2365073	MAS = 3.1/8 **Moderately irritating**
Skin Sensitization, Maximization Hartley albino guinea pigs PMRA 2365083	Positive erythema reactions in 20/20 test sites at 6% w/w and 14/20 sites at 2% w/w **Potential skin sensitizer**

Study Type/ Animal/ PMRA Document Number	**Study Results**
Acute Toxicity Studies – OXTP 200SC Fungicide and Dupont *Zorvec* Enicade	
Acute Oral Toxicity (gavage) Sprague Dawley rats PMRA 2365221	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute Dermal Toxicity Sprague Dawley rats PMRA 2365223	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute Inhalation Toxicity Sprague Dawley rats PMRA 2365225	LC_{50} > 5.1 mg/L **Low toxicity**
Eye Irritation NZW rabbits PMRA 2365232	MAS = 0/110 **Non irritating**
Dermal Irritation NZW rabbits PMRA 2365230	MAS = 0/8 **Non irritating**
Skin Sensitization, Maximization Hartley albino guinea pigs PMRA 2365233	Very faint erythema in 9/20 test sites **Not a potential skin sensitizer**

Table 2 Toxicity Profile of Technical Oxathiapiprolin

(Effects are known or assumed to occur in both sexes unless otherwise noted; sex specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted.)

Study Type/ Animal/ PMRA Document Number	Study Results
Toxicokinetic Studies	
Metabolism and pharmacokinetics, gavage, PMRA document number: 2365155, 2365156 98.9% pure, radiolabeled on isoxazoline ring or the pyrazole ring 4-20 Sprague Dawley rats/sex/group, low dose = 10 mg/kg bw, high dose = 200 mg/kg bw Oxathiapiprolin and its metabolites were readily excreted by the rat with fecal excretion as the major route of elimination for all animals after low-and high-dose administration. Expiration as carbon dioxide or other volatile compounds was not a significant route of elimination. Retention of oxathiapiprolin or its metabolites in tissues and blood was negligible indicating very low potential for bioaccumulation. No individual tissue contained levels exceeding 0.04% of the dose by 168 hours after dose administration. In the low-dose groups (10 mg/kg bw), absorption was 31-49%. Absorption at the high dose (200 mg/kg bw) was saturated and averaged 5-8%. The metabolism of oxathiapiprolin involved multiple reaction sites including hydroxylation in various positions. The multiple reactions contributed too many identified and tentatively identified low level metabolites in feces, urine, and bile. Unmetabolized oxathiapiprolin was the chief component recovered in feces and accounted for 17-87% of the administered low-or high-dose of either label. Toxicokinetics and metabolism were also examined with multiple, repeat-doses of oxathiapiprolin for 14 days. Similarities between peak and minimum plasma and tissue concentrations across time following single doses suggest steady-state kinetic behaviour in male and female rats. After cessation of dosing, the ^{14}C residues were readily eliminated from tissues and plasma. The overall tissue distribution in male and female rats was similar to that found after single dose administration and confirmed no accumulation in fat or muscle and very low potential for accumulation in liver, kidney and red blood cells. Excretion of parent oxathiapiprolin in the feces was the predominant route of elimination, with urinary elimination of cleaved metabolites playing a minor role. Metabolism of systemically absorbed dose was extensive and characterized by numerous identified and tentatively identified components in feces, urine and plasma. The material balance and profile of metabolites were consistent with that observed in the single dose study. Analyses of dose preparation and the liver for the two enantiomers of oxathiapiprolin, IN-Q7N25 ((*S*)-oxathiapiprolin) and IN-Q7N24 ((*R*)-oxathiapiprolin), showed that metabolism of IN-Q7N24 ((*R*)-oxathiapiprolin) was favoured three to fourfold over IN-Q7N25 ((*S*)-oxathiapiprolin). Radiolabel concentrations in tissue and plasma samples following single or multiple doses showed no significant potential for bioaccumulation of oxathiapiprolin or its metabolites.	

Study Type/ Animal/ PMRA Document Number	Study Results
Acute Toxicity Studies – Technical	
Acute Oral Toxicity (gavage) Sprague Dawley rats **PMRA** 2365151	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute Dermal Toxicity Sprague Dawley rats **PMRA** 2365149	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute Inhalation Toxicity Sprague Dawley rats **PMRA** 2365147	LC_{50} > 5.1 mg/L **Low toxicity**
Eye Irritation NZW rabbits **PMRA** 2365145	MAS = 1/110 **Minimally irritating**
Dermal Irritation NZW rabbits **PMRA** 2365145	MAS = 0/8 **Non-irritating**
Skin Sensitization, Maximization Hartley albino guinea pigs **PMRA** 2365141	Very faint erythema in 1/20 test sites **Not a potential skin sensitizer**
Short-Term Toxicity Studies	
28-Day Dermal Toxicity Sprague Dawley rats **PMRA** 2365108	NOAEL = 1000 mg/kg bw/day No adverse effects
28-Day Oral Toxicity (diet) CD-1 mice **PMRA** 2365125	NOAEL = 1151/1400 mg/kg bw/day (♂/♀) No adverse effects

Study Type/ Animal/ PMRA Document Number	Study Results
2365128	
90-Day Oral Toxicity (diet) CD-1 mice PMRA 2365124	NOAEL = 1058/1468 mg/kg bw/day ♂/♀ No adverse effects
14-Day Oral Toxicity (gavage) with in vivo Micronucleus Assay Sprague Dawley rats PMRA 2365139	Supplemental, non-GLP No adverse effects Negative for micronuclei
28-Day Oral Toxicity (diet) Sprague Dawley rats PMRA 2365135, 2365137	Supplemental, range-finding No adverse effects at 1657/1774 mg/kg bw/day ♂/♀
90-Day Oral Toxicity (diet) with FOB Sprague Dawley rats PMRA 2365122	NOAEL = 1096/1300 mg/kg bw/day ♂/♀ No adverse effects No FOB or motor activity effects
28-Day Oral Toxicity (diet) Beagle dogs PMRA 2365130, 2365132	NOAEL = 1368/1346 mg/kg bw/day ♂/♀ No adverse effects
90-Day Oral Toxicity (diet) Beagle dogs PMRA 2365117, 2365119	NOAEL = 1415/1429 mg/kg bw/day ♂/♀ No adverse effects
1-Year Toxicity (diet) Beagle dogs PMRA 2365113	NOAEL = 1242/1461 mg/kg bw/day ♂/♀ No adverse effects

Study Type/ Animal/ PMRA Document Number	Study Results
Chronic Toxicity/Oncogenicity Studies	
1.5-Year Oncogenicity (diet) CD-1 mice PMRA 2365081	NOAEL = 948/1106 mg/kg bw/day ♂/♀ No adverse effects No evidence of oncogenicity
Combined 1-Year Oral Toxicity and 2-Year Oncogenicity (diet) Sprague Dawley rats PMRA 23265088	NOAEL = 735/957 mg/kg bw/day ♂/♀ No adverse effects No evidence of oncogenicity
Developmental/Reproductive Toxicity Studies	
One-Generation Reproductive Toxicity (diet) Sprague Dawley rats PMRA 2365068	Supplemental, range-finding Parental toxicity No adverse effects Reproductive toxicity No adverse effects Offspring toxicity **1948 mg/kg bw/day:** ↓ bw, bwg; ↑ time to preputial separation ♂
Two-Generation Reproductive Toxicity (diet) Sprague Dawley rats PMRA 2365053, 2454561	Parental toxicity NOAEL = 1013/1210 mg/kg bw/day ♂/♀ No adverse effects Reproductive toxicity NOAEL = 1013/1210 mg/kg bw/day ♂/♀ No adverse effects Offspring toxicity NOAEL = 411 mg/kg bw/day **1196 mg/kg bw/day:** ↓ bw, bwg (F_2), ↑ time to preputial separation ♂ Evidence of sensitivity of the young
Developmental Toxicity (gavage) Sprague Dawley rats	Maternal toxicity NOAEL = 1000 mg/kg bw/day No adverse effects

Study Type/ Animal/ PMRA Document Number	Study Results
PMRA 2365049	Developmental toxicity NOAEL = 1000 mg/kg bw/day No adverse effects No evidence of sensitivity of the young
Developmental Toxicity (gavage) New Zealand White rabbits PMRA 2365046	Maternal toxicity NOAEL = 1000 mg/kg bw/day No adverse effects Developmental toxicity NOAEL = 1000 mg/kg bw/day No treatment-related effects No evidence of sensitivity of the young
Genotoxicity Studies	
Bacterial Gene Mutation Assay (in vitro) *Salmonella/Escherichia* TA98, TA100, TA1535, TA1537, WP2 uvrA PMRA 2365106	Negative
Mammalian Gene Mutation Assay (in vitro) CHO-K_1 cells PMRA 2365101	Negative
Mammalian Chromosome Aberration Assay (in vitro) Human peripheral blood lymphocytes PMRA 2365103	Negative

Study Type/ Animal/ PMRA Document Number	Study Results
Mammalian Micronucleus Assay (in vivo) CD-1 mice PMRA 2365099	Negative
Neurotoxicity Studies	
Acute Neurotoxicity (gavage) Sprague Dawley rats PMRA 2365038	NOAEL = 2000 mg/kg bw No adverse effects
Immunotoxicity Studies	
Immunotoxicity (diet) ELISA CD-1 mice	NOAEL = 1432 mg/kg bw/day No evidence of changes to humoral immune function or spleen or thymus weight No evidence of immunotoxicity
Special Studies	
Steroidogenesis assay H295R human cell line PMRA 2365041	Negative for effects on testosterone and estradiol
Uterotrophic Assay for Detecting Endocrine Activity Sprague Dawley rats PMRA 2365043	No induction of estrogenic effects in ovariectomised adult female rats
Intact Male Assay for Detecting Endocrine Activity Sprague Dawley rats PMRA 2365045	No alterations of endocrine activity in adult male rats

Study Type/ Animal/ PMRA Document Number	Study Results
Metabolites	
IN-E8S72 28-Day Oral Toxicity (diet) Sprague Dawley rats PMRA 2365026	Supplemental, range-finding No adverse effects at the limit dose
IN-E8S72 Bacterial Gene Mutation Assay (in vitro) *Salmonella/Escherichia* TA98, TA100, TA1535, TA1537, WP2 uvrA PMRA 2365000	Negative
IN-E8S72 Mammalian Chromosome Aberration Assay (in vitro) Human peripheral blood lymphocytes PMRA 2365029	Positive for structural aberrations (chromosome breaks) at 1800 µg/mL ±S9, negative for numerical aberrations Cell toxicity at 1800 µg/mL ± metabolic activation
IN-E8S72 Mammalian Gene Mutation Assay (in vitro) CHO-K_1 cells PMRA 2365032	Negative
IN-E8S72 Mammalian Micronucleus Assay (in vivo) CD-1 mice PMRA 2365035	Negative
IN-RAB06 Bacterial Gene Mutation Assay (in vitro) *Salmonella/Escherichia* TA98, TA100, TA1535,	Negative

Study Type/ Animal/ PMRA Document Number	Study Results
TA1537, WP2 uvrA PMRA 2365019	
IN-RAB06 Mammalian Chromosome Aberration Assay (in vitro) Human peripheral blood lymphocytes PMRA 2365023	Negative
IN-RAB06 Mammalian Gene Mutation Assay (in vitro) CHO-K_1 cells PMRA 2365017	Negative
IN-RDT31 Bacterial Gene Mutation Assay (in vitro) *Salmonella/Escherichia* TA98, TA100, TA1535, TA1537, WP2 uvrA PMRA 2365015	Negative
IN-RDT31 Mammalian Chromosome Aberration Assay (in vitro) Human peripheral blood lymphocytes PMRA 2365011	Negative
IN-RDT31 Mammalian Gene Mutation Assay (in vitro) CHO-K_1 cells PMRA 2365013	Negative
IN-SXS67 Bacterial Gene Mutation Assay (in vitro)	Negative

Study Type/ Animal/ PMRA Document Number	Study Results
Salmonella/Escherichia TA98, TA100, TA1535, TA1537, WP2 uvrA PMRA 2365007	
IN-SXS67 Mammalian Chromosome Aberration Assay (in vitro) Human peripheral blood lymphocytes PMRA 2365003	Negative
IN-WR791 Bacterial Gene Mutation Assay (in vitro) *Salmonella/Escherichia* TA98, TA100, TA1535, TA1537, WP2 uvrA PMRA 2365000	Negative
IN-WR791 Mammalian Chromosome Aberration Assay (in vitro) Human peripheral blood lymphocytes PMRA 2364995	Negative

Table 3 **Toxicology Endpoints for Use in Health Risk Assessment for Oxathiapiprolin**

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or MOE
Acute dietary	No relevant endpoint identified		
Repeated dietary	Rat oral (dietary) 2-generation reproductive toxicity	NOAEL = 411 mg/kg bw/day Decreased offspring body weight, body-weight gain and increased time to preputial separation	100
	ADI = 4 mg/kg bw/day		
Short, intermediate and long-term dermal	No relevant endpoint identified		
Short and Intermediate-term inhalation	Rat oral (dietary) 2-generation reproductive toxicity	Adjusted NOAEL[2] = 20 mg/kg bw/day Decreased offspring body weight, body weight gain and increased time to preputial separation	100
Cancer	No relevant endpoint identified		

[1] CAF (composite assessment factor) refers to a total of uncertainty and PEST CONTROL PRODUCTS ACT factors for dietary risk assessment; MOE refers to the target margin of exposure for occupational assessment.

[2] Since GI absorption was only approximately 5% at high dose levels and compound absorption by the inhalation route is assumed to be 100%, the original oral NOAEL of 411 mg/kg bw/day was multiplied by a 5% correction factor to obtain a systemic NOAEL (411*0.05=20) for inhalation exposure scenarios.

Table 4 **Residue Analysis**

Matrix	Method ID	Analyte	Method Type	LOQ		PMRA Document Number
Plant	DuPont-30422 Supplement 1 **(Enforcement method in plant matrices)**	Oxathiapiprolin, IN-SXS67, IN-RZB20, IN-RZD74, IN-E8S72, IN-WR791, IN-RDG40, IN-Q7H09	LC-MS/MS	0.01 ppm	Wheat (forage, grain, straw), potato (tuber and chips), grape (fruit and dry pomace), tomato (fruit and juice), spinach, broccoli, whole pepper, dried soybean seed, dried beans, dry bulb onion, dried ginseng, dried tobacco leaves, canola seed, orange, carrot root, hops	2365222, 2365224, 2365193, 2365190, 2365196, 2365208, 2365212, 2365220
	DFG S19	Oxathiapiprolin, IN-RZB20, IN-RZD74, IN-E8S72, IN-WR791, IN-RDG40, IN-Q7H09	LC-MS/MS	0.01 ppm	Apple, citrus, barley grain, tomato	2365182, 2365200, 2365210

Matrix	Method ID	Analyte	Method Type	LOQ		PMRA Document Number
	QuEChERS	Oxathiapiprolin	LC-MS/MS	0.01 ppm	Lettuce, wheat grain, corn grain, whole orange	2365186 2365210
Animal	DuPont-31138 **(Enforcement method in animal matrices)**	Oxathiapiprolin, IN-Q7H09, IN-RDG40, IN-RLB67, IN-RAB06	LC-MS/MS	0.01 ppm	Bovine meat, fat, liver and kidney; milk, cream, eggs	2365226, 2365205
	DFG S19	Oxathiapiprolin, IN-Q7H09, IN-RDG40, IN-RLB67, IN-RAB06	LC-MS/MS	0.01 ppm	Bovine meat, fat, liver and kidney; milk, eggs	2365180, 2365203, 2365210
Fish		oxathiapiprolin	HPLC-MS-MS	0.010 mg/kg	Whole fish	2365214 2365216
Soil		oxathiapiprolin IN-QPS10 IN-RDT31 IN-RAB06 IN-E8S72	HPLC-MS-MS	1 µg/kg in silt loam and clay loam soils		2365173 2365174 2365170
Sediment				Extended from soil		
Water		oxathiapiprolin IN-QPS10 IN-RDT31 IN-RAB06 IN-E8S72 IN-Q7D41 IN-P3X26	HPLC-MS-MS	0.1 µg/kg in drinking, ground and surface water		2365164 2365166 2365162

Table 5 Integrated Food Residue Chemistry Summary

FOLIAR TREATMENT			
NATURE OF THE RESIDUE IN LETTUCE			**PMRA Document Number: 2364967**
Radiolabel Position	[Pyrazole-5-^{14}C] and [Thiazole-5-^{14}C]		
Test Site	Outdoor treatment plots (1m^2)		
Treatment	Foliar treatment		
Total Rate	Three 70 g ai/ha applications; total rate of 210 g ai/ha		
Formulation	Formulated with oil dispersion (OD) inert ingredients		
Preharvest interval	14 days (at maturity); immature samples were also collected at 0 and 10 days after treatment 1, at 0 and 10 days after treatment 2, and at 0, 3 and 7 days after treatment 3		
Matrices	**PHI (days)**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**
		TRRs (ppm)	**TRRs (ppm)**
Lettuce leaves	0DAT1	5.392	11.286
	10DAT1	0.719	0.518
	0DAT2	5.514	5.780
	10DAT2	0.488	0.927
	0DAT3	4.729	4.583

	3DAT3	1.272	2.627
	7DAT3	0.626	0.669
	14DAT3	0.520	0.473

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**
Lettuce leaves (3DAT3)	OXP (79%)	OXP (85%)	IN-Q7H09, IN-Q7D41, Hydroxylated OXP compounds	IN-Q7H09, IN-Q7D41, Hydroxylated OXP compounds, IN-Q7D13
Lettuce leaves (7DAT3)	OXP (77%)	OXP (75%)	IN-Q7H09, IN-Q7D41	Hydroxylated OXP compounds
Lettuce leaves (14DAT3)	OXP (65%)	OXP (57%)	IN-Q7H09, IN-Q7D41, Hydroxylated OXP compounds	IN-Q7H09, IN-Q7D41, Hydroxylated OXP compounds

The primary metabolic pathway of oxathiapiprolin in lettuce following foliar treatment was hydroxylation in various positions of the molecule.

NATURE OF THE RESIDUE IN POTATO	**PMRA Document Number: 2364982**
Radiolabel Position	[Pyrazole-5-^{14}C] and [Thiazole-5-^{14}C]
Test Site	Outdoor treatment plots (1m^{2})
Treatment	Foliar treatment
Total Rate	Three 70 g ai/ha applications; total rate of 210 g ai/ha
Formulation	Formulated with oil dispersion (OD) inert ingredients
Preharvest interval	Tubers: 14 and 28 days; immature samples were also collected at 14 days after treatment 2; Foliage: At 0 and 14 days after treatment 1, at 0 and 14 days after treatment 2, and at 0, 14 and 28 days after treatment 3

Matrices	**PHI (days)**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**
		TRRs (ppm)	**TRRs (ppm)**
Potato tubers	14DAT2	0.003	0.003
	14DAT3	0.009	0.004
	28DAT3	0.012	0.005
Potato foliage	14DAT1	0.694	0.894
	0DAT2	1.735	5.938
	14DAT2	0.819	1.317
	14DAT3	0.918	0.993
	28DAT3	0.162	0.255

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**
Potato foliage (14DAT1)	OXP (54%)	OXP (48%)	Hydroxymethyl-pyrazole glucoside of OXP-diol, glucose conjugate of IN-RPD37, hydroxylated OXP compounds, IN-Q7H09, IN-Q7D41	Hydroxymethyl-pyrazole glucoside of OXP-diol, glucose conjugate of IN-RPD37, hydroxylated OXP compounds, IN-Q7H09, IN-Q7D41, IN-RDG40

Potato foliage (14DAT2)	OXP (40%)	OXP (59%)	Hydroxymethyl-pyrazole glucoside of OXP-diol, IN-RDG40, hydroxylated OXP compounds, IN-Q7H09, IN-Q7D41	Glucose conjugate of IN-RPD17, hydroxylated OXP compounds, IN-Q7H09, IN-Q7D41, IN-RDG40
Potato foliage (14DAT3)	OXP (40%)	OXP (43%)	Hydroxymethyl-pyrazole glucoside of OXP-diol, glucose conjugate of IN-RPD17, hydroxylated OXP compounds, IN-Q7H09, IN-RDG40	Hydroxymethyl-pyrazole glucoside of OXP-diol, glucose conjugate of IN-RPD17, hydroxylated OXP compounds, IN-Q7H09, IN-RDG40
Potato foliage (28DAT3)	OXP (25%)	OXP (42%)	Hydroxymethyl-pyrazole glucoside of OXP-diol, glucose conjugate of IN-RPD17, hydroxylated OXP compounds, IN-Q7H09	Hydroxymethyl-pyrazole glucoside of OXP-diol, glucose conjugate of IN-RPD17, hydroxylated OXP compounds, IN-RDG40

The primary metabolic pathway of oxathiapiprolin in potato plants following foliar treatment was hydroxylation in various positions of the molecule followed by glucose conjugation.

NATURE OF THE RESIDUE IN GRAPES	**PMRA Document Number: 2369969**
Radiolabel Position	[Pyrazole-5-^{14}C] and [Thiazole-5-^{14}C]
Test Site	Vines growing outdoors in plastic containers
Treatment	Foliar treatment
Total Rate	Three 70 g a/ha applications; total rate of 210 g a/ha
Formulation	Formulated with oil dispersion (OD) inert ingredients
Preharvest interval	Berries: 76 days; immature samples were also collected at 14 days after treatment 2, and at 0 and 14 days after treatment 3; Foliage: At 0 days after treatment 1, at 0 and 14 days after treatment 2, and at 0, 14 and 76 days after treatment 3

Matrices	**PHI (days)**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**
		TRRs (ppm)	**TRRs (ppm)**
Grape berries	14DAT2	0.340	0.248
	0DAT3	0.468	0.463
	14DAT3	0.461	0.545
	76DAT3	0.304	0.318
Grape foliage	0DAT1	14.969	15.428
	0DAT2	32.451	23.011
	14DAT2	7.218	16.319
	0DAT3	37.536	28.617
	14DAT3	10.911	8.589
	76DAT3	1.381	1.116

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**
Grape berries (14DAT3)	OXP (36%), IN-E8S72 (13%), IN-WR791 (15%)	OXP (74%)	IN-RAB06, IN-RDG40, IN-Q7H09, IN-Q7D41, IN-K1552	IN-RAB06, IN-RDG40, IN-Q7H09, IN-Q9L80, IN-QPS10

Grape berries (76DAT3)	OXP (10%), IN-E8S72 (14%), IN-WR791 (19%)	OXP (41%)	IN-RDG40, IN-SXS67, IN-RZB20	IN-RDG40, IN-Q7H09, IN-Q7D41, IN-Q9R70
Grape foliage (0DAT1)	OXP (98%)	OXP (92%)	—	IN-RAB06, IN-RDG40, IN-Q7D41
Grape foliage (14DAT2)	OXP (64%)	OXP (92%)	IN-RAB06, IN-RDG40, IN-Q7H09, IN-Q7D41, IN-WR791, IN-KJ552	IN-Q7D41
Grape foliage (14DAT3)	OXP (66%)	OXP (82%)	IN-RAB06, IN-RDG40, IN-Q7H09, IN-Q7D41, IN-WR791, IN-KJ552	IN-RAB06, IN-RDG40, IN-Q7H09, IN-Q7D41, IN-Q9E80, IN-QPS10
Grape foliage (76DAT3)	OXP (32%)	OXP (60%)	IN-RDG40, IN-Q7H09, IN-Q7D41, IN-E8S72, IN-WR791, IN-KJ552, IN-SXS67, IN-RZB20	IN-RAB06, IN-RDG40, IN-Q7H09, IN-Q7D41, IN-QPS10

The primary metabolic pathways of oxathiapiprolin in grapes following foliar treatment were hydroxylation, reduction within the isoxazoline ring, cleavage between the piperidine and pyrazole rings, and N-glucose conjugation.

SOIL TREATMENT

NATURE OF THE RESIDUE IN LETTUCE	**PMRA Document Number: 2360976**
Radiolabel Position	[Pyrazole-5-^{14}C] and [Isoxazoline-5-^{14}C]
Test Site	Heated glasshouse compartments
Treatment	Soil treatment
Total Rate	One application at 600 g a.i/ha
Formulation	Formulated with suspension concentrate (SC) inert ingredients
Preharvest interval	57 days (at maturity); immature samples were also collected at 30 and 44 days after treatment

Matrices	**PHI (days)**	**[Pyrazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**
		TRRs (ppm)	**TRRs (ppm)**
Lettuce leaves	44	0.029	<0.008
	57	0.018	0.006

Metabolites Identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**	**[Pyrazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**
Immature lettuce leaves (44DAT)	IN-RZB21/RZD74 (21%), IN-E8S72 (19%), IN-WR791 (23%)	Not analysed further	IN-SXS67, IN-RZB20	Not analysed further
Mature lettuce leaves (57DAT)	IN-RZB21/RZD74 (19%), IN-E8S72 (21%), IN-WR791 (30%)	Not analysed further	IN-SXS67, IN-RZB20, IN-KJ552	Not analysed further

NATURE OF THE RESIDUE IN POTATO	**PMRA Document Number: 2360972**
Radiolabel Position	[Pyrazole-5-^{14}C] and [Isoxazoline-5-^{14}C]
Test Site	Heated glasshouse compartments
Treatment	Soil treatment
Total Rate	One application at 600 g a.i/ha
Formulation	Formulated with suspension concentrate (SC) inert ingredients
Preharvest interval	Tubers and foliage: 57 and 72 days

Matrices	**PHI (days)**	**[Pyrazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**
		TRRs (ppm)	**TRRs (ppm)**
Potato tubers	57	0.023	0.013
	72	0.013	0.006
Potato foliage	57	0.026	0.021
	72	0.108	0.076

Metabolites Identified	Major Metabolites (>10% of the TRRs)		Minor Metabolites (<10% of the TRRs)	
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**	**[Pyrazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**
Potato tubers (57DAT)	IN-RZB20 (12%), IN-WR791 (14%)	Not analysed further	ONP, IN-SXS67, IN-RZB21/RZD74, IN-E8S72, IN-KJ552	Not analysed further
Potato tubers (72DAT)	IN-RZB20 (12%), IN-E8S72 (14%), IN-WR791 (25%)	Not analysed further	IN-SXS67, IN-RZB21/RZD74, IN-KJ552	Not analysed further
Potato foliage (57DAT)	IN-RZB20 (13%), IN-RZB21/RZD74 (19%), IN-E8S72 (12%), IN-WR791 (13%)	Unknown compound eluting at 29.50 min	IN-SXS67, IN-KJ552	Unknown compounds eluting at 26.50 min, 33.50 min
Potato foliage (72DAT)	IN-RZB20 (12%), IN-RZB21/RZD74 (15%)	—	ONP, IN-SXS67, IN-E8S72, IN-WR791, IN-KJ552	ONP

NATURE OF THE RESIDUE IN COURGETTE	**PMRA Document Number: 2564977**
Radiolabel Position	[Pyrazole-5-^{14}C] and [Isoxazoline-5-^{14}C]
Test Site	Heated glasshouse compartments
Treatment	Soil treatment
Total Rate	One application at 600 g a.i/ha
Formulation	Formulated with suspension concentrate (SC) inert ingredients
Preharvest interval	Fruit and foliage: 68 and 79 days

Matrices	PHI (days)	[Pyrazole-5-^{14}C]	[Isoxazoline-5-^{14}C]
		TRRs (ppm)	TRRs (ppm)
Courgette fruit	68	0.015	0.006
	79	0.025	0.006
Courgette foliage	68	0.067	0.028
	79	0.170	0.008

Metabolites Identified	Major Metabolites (>10% of the TRRs)		Minor Metabolites (<10% of the TRRs)	
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**	**[Pyrazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**
Courgette fruit (68DAT)	IN-WR791 (57%)	Not analysed further	ONP, IN-SXS67, IN-RZB20, IN-RZB21/RZD74, IN-E8S72, IN-KJ552	Not analysed further
Courgette fruit (79DAT)	IN-WR791 (58%)	Not analysed further	IN-SXS67, IN-RZB20, IN-RZB21/RZD74, IN-E8S72, IN-KJ552	Not analysed further
Courgette foliage (68DAT)	IN-RZB20 (17%), IN-RZB21/RZD74 (15%), IN-E8S72 (24%), IN-WR791 (24%)	ONP (24%), Region 2 (13%), IN-Q7H09 (19%)	IN-SXS67, IN-KJ552	—
Courgette foliage (79DAT)	IN-RZB20 (12%), IN-RZB21/RZD74 (11%), IN-E8S72 (21%), IN-WR791 (38%)	Not analysed further	ONP, IN-SXS67, IN-KJ552, IN-Q7H09	Not analysed further

The primary metabolic pathways of oxathiapiprolin in lettuce, potato and courgette following soil treatment were cleavage between the piperidine and pyrazole rings followed by further oxidation to form the pyrazole-containing polar metabolites, and subsequent glucose conjugation. Hydroxylation of oxathiapiprolin was also detected.

CONFINED ACCUMULATION IN ROTATIONAL CROPS – Wheat, lettuce and turnip				PMRA Document Number: [illegible]
Radiolabel Position	[Pyrazole-5-^{14}C], [Thiazole-5-^{14}C] and [Isoxazoline-5-^{14}C]			
Test site	Open wood-framed crates in temperature-controlled glasshouse			
Formulation	Formulated with oil dispersion (OD) inert ingredients			
Application rate and timing	Bare soil was treated at 300 g a.i./ha, and aged for 30, 120 and 365 days			
Matrices	**PBI (days)**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**
Spring wheat grain	30	0.258	0.007	0.015
	120	0.097	0.003	0.017
	365	<0.007	<0.008	<0.006
Spring wheat forage	30	0.269	0.017	0.007
	120	0.172	0.010	<0.010
	365	0.025	<0.009	<0.006
Spring wheat hay	30	0.298	0.018	0.009
	120	0.172	0.015	0.007
	365	0.081	0.006	<0.008
Spring wheat straw	30	0.768	0.055	0.026
	120	0.500	0.055	0.040
	365	0.166	0.008	0.002
Immature lettuce leaves	30	0.028	0.004	<0.006
	120	0.028	<0.004	<0.009
	365	<0.010	<0.006	<0.007
Mature lettuce leaves	30	0.015	0.002	<0.008
	120	0.025	<0.004	<0.008
	365	0.006	<0.008	<0.007
Immature turnip foliage	30	0.095	0.005	<0.008
	120	0.088	<0.005	<0.008
	365	0.018	<0.009	<0.008
Mature turnip foliage	30	0.122	0.007	<0.010
	120	0.176	<0.006	<0.009
	365	0.016	<0.010	<0.006
Turnip tubers	30	0.018	0.006	0.006
	120	0.025	0.004	0.007
	365	0.008	0.010	<0.004

Metabolites Identified		**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Matrices	**PBI (days)**	**[Pyrazole-5-^{14}C]**	**[Pyrazole-5-^{14}C]**
Spring wheat grain	30	IN-E8S72 (17%), IN-WR791 (38%)	[illegible] and nonpolar metabolites, IN-SXS67, IN-RZB20, IN-RZD31/RZD74
	120	IN-E8S72 (30%), IN-WR791 (22%), IN-SXS67 (10%)	[illegible] and nonpolar metabolites, IN-RZB20, IN-RZD31/RZD74
Spring wheat forage	30	IN-WR791 (42%), IN-SXS67 (18%), IN-RZB20 (10%)	[illegible] and nonpolar metabolites, IN-E8S72, IN-RZD31/RZD74
	120	IN-E8S72 (12%), IN-SXS67 (50%)	IN-WR791, IN-RZB20, IN-RZD31/RZD74

	365	IN-RZB20 (55%)	IN-E8S72, IN-SXS67
Spring wheat hay	30	IN-E8S72 (16%), IN-WR791 (19%), IN-SXS67 (18%), IN-RZB20 (21%), IN-RZB21/RZD74 (10%)	OXP and nonpolar metabolites
	120	IN-E8S72 (17%), IN-SXS67 (56%)	IN-WR791, IN-RZB20, IN-RZB21/RZD74
	365	IN-SXS67 (18%), IN-RZB20 (43%)	IN-E8S72, IN-RZB21/RZD74
Spring wheat straw	30	IN-E8S72 (13%), IN-SXS67 (20%), IN-RZB20 (27%)	OXP and nonpolar metabolites, IN-WR791, IN-RZB21/RZD74, IN-KJ552
	120	IN-E8S72 (14%), IN-SXS67 (48%), IN-RZB20 (13%)	IN-WR791, IN-RZB21/RZD74
	365	IN-SXS67 (57%)	IN-E8S72, IN-WR791, IN-RZB20, IN-RZB21/RZD74
Immature lettuce leaves	30	IN-E8S72 (21%), IN-WR791 (31%)	IN-Q7D41
	120	IN-E8S72 (76%)	IN-WR791
Mature lettuce leaves	30	IN-E8S72 (11%), IN-WR791 (12%)	—
	120	IN-E8S72 (48%)	OXP and nonpolar metabolites, IN-WR791, IN-SXS67, IN-RZB20, IN-RZB21/RZD74
Turnip tubers	30	IN-E8S72 (19%), IN-WR791 (49%)	—
	120	OXP and nonpolar metabolites (15%), IN-E8S72 (18%), IN-WR791 (10%)	—
Immature turnip foliage	30	IN-E8S72 (21%), IN-WR791 (52%), IN-RZB20 (12%)	IN-SXS67, IN-RZB21/RZD74
	120	IN-E8S72 (73%), IN-WR791 (32%), IN-RZB20 (10%)	IN-RZB21/RZD74
	365	IN-E8S72 (19%), IN-WR791 (26%), IN-RZB20 (10%), IN-RZB21/RZD74 (10%)	—
Mature turnip foliage	30	IN-E8S72 (20%), IN-WR791 (45%), IN-RZB20 (10%), IN-SXS67 (10%)	IN-RZB21/RZD74
	120	IN-E8S72 (48%), IN-WR791 (19%)	IN-SXS67, IN-RZB20, IN-RZB21/RZD74, IN-RZB20 (6%)
	365	IN-E8S72 (12%), IN-WR791 (46%), IN-RZB20 (11%), IN-RZB21/RZD74 (32%)	—
Metabolites Identified		**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Matrices	**PHI (days)**	**[Isoxazoline-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**
Wheat straw	30	OXP and nonpolar metabolites (13%)	—
	120	IN-QPS10 (12%)	—
CONFINED ACCUMULATION IN ROTATIONAL CROPS – Wheat, lettuce and turnip			**PMRA Document Number: 2364859**
Radiolabel Position		[Pyrazole-5-^{14}C] and [Isoxazoline-5-^{14}C]	
Test site		Open wooden-sided crates in temperature-controlled glasshouses	
Formulation		Formulated with suspension concentrate (SC) inert ingredients	
Application rate and timing		Bare soil was treated at **600 g a.i./ha**; primary crops (courgette, lettuce, potato) were sown and maintained until harvest; rotational crops (wheat, turnip, lettuce) were sown onto same treated soil at 30, 120 and 365 days after treatment.	

Matrices	PBI (days)	[Pyrazole-5-^{14}C]	[Isoxazoline-5-^{14}C]
Spring wheat grain	30	0.135	0.016
	120	0.191	0.017
	365	0.117	0.008
Spring wheat forage	30	0.066	0.017
	120	0.168	0.017
	365	0.234	0.008
Spring wheat hay	30	0.263	0.018
	120	0.142	0.010
	365	0.226	0.011
Spring wheat straw	30	0.697	0.091
	120	0.668	0.094
	365	0.477	0.057
Immature lettuce leaves	30	0.025	0.002
	120	0.036	<0.001
	365	0.036	0.004
Mature lettuce leaves	30	0.020	0.006
	120	0.031	0.002
	365	0.024	0.003
Immature turnip foliage	30	0.107	0.010
	120	0.024	0.004
	365	0.044	0.009
Mature turnip foliage	30	0.086	0.011
	120	0.031	0.007
	365	0.043	0.004
Turnip tubers	30	0.020	0.016
	120	0.011	0.006
	365	0.016	0.004

Metabolites Identified		**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Matrices	**PBI (days)**	**[Pyrazole-5-^{14}C]**	**[Pyrazole-5-^{14}C]**
Spring wheat grain	30	IN-E8S72 (14%), IN-WR791 (23%), IN-SXS67 (10%), IN-RZB20 (10%)	IN-RZB21/RZD74, IN-KJ552
	120	IN-WR791 (25%)	IN-E8S72, IN-SXS67, IN-RZB20, IN-RZB21/RZD74, IN-KJ552
	365	IN-WR791 (37%), IN-RZB20 (13%)	IN-E8S72, IN-SXS67
Spring wheat forage	30	IN-WR791 (14%), IN-SXS67 (24%), IN-RZB20 (11%), IN-RZB21/RZD74 (12%), unknown compound eluting at *ca.* 12 min (12%)	IN-E8S72, IN-KJ552
	120	IN-WR791 (13%), IN-SXS67 (37%), IN-RZB21/RZD74 (14%)	IN-E8S72, IN-RZB20, IN-KJ552
	365	IN-E8S72 (12%), IN-WR791 (31%), IN-SXS67 (21%), IN-RZB21/RZD74 (10%)	OXP and nonpolar metabolites, IN-RZB20, IN-KJ552

Spring wheat hay	30	IN-SXS67 (35%), IN-RZB20 (19%), IN-RZB21/RZD74 (13%)	IN-E8S72, IN-WR791, IN-KJ552
	120	IN-SXS67 (30%), IN-RZB20 (13%), IN-RZB21/RZD74 (14%)	IN-E8S72, IN-WR791, IN-KJ552
	365	IN-WR791 (10%), IN-SXS67 (26%), IN-RZB20 (17%), IN-RZB21/RZD74 (12%)	IN-E8S72, IN-KJ552
Spring wheat straw	30	IN-SXS67 (39%), IN-RZB20 (17%), IN-RZB21/RZD74 (12%)	IN-E8S72, IN-WR791, IN-KJ552
	120	IN-SXS67 (26%), IN-RZB20 (22%), IN-RZB21/RZD74 (15%)	IN-E8S72, IN-WR791, IN-KJ552
	365	IN-SXS67 (26%), IN-RZB20 (26%), IN-RZB21/RZD74 (12%)	IN-E8S72, IN-WR791
Immature lettuce leaves	30	IN-E8S72 (20%), IN-WR791 (27%), IN-RZB20 (14%)	IN-SXS67, IN-RZB21/RZD74, IN-KJ552
	120	IN-E8S72 (25%), IN-WR791 (20%), IN-RZB21/RZD74 (14%)	IN-SXS67, IN-RZB20, IN-KJ552
	365	IN-E8S72 (35%), IN-WR791 (24%), IN-RZB21/RZD74 (14%)	OXP and nonpolar metabolites, IN-SXS67, IN-RZB20, IN-KJ552
Mature lettuce leaves	30	IN-E8S72 (22%), IN-WR791 (34%), IN-RZB21/RZD74 (21%)	IN-SXS67, IN-RZB20, IN-KJ552
	120	IN-E8S72 (21%), IN-WR791 (20%), IN-RZB21/RZD74 (15%)	IN-SXS67, IN-RZB20, IN-KJ552
	365	IN-E8S72 (33%), IN-WR791 (27%), IN-RZB21/RZD74 (18%)	IN-SXS67, IN-RZB20, IN-KJ552
Turnip tubers	30	IN-RZB21/RZD74 (14%)	IN-E8S72, IN-WR791, IN-SXS67, IN-RZB20, IN-KJ552, unknown compound eluting at *ca.* 19 min
	365	IN-WR791 (17%), IN-KJ552 (10%)	IN-E8S72, IN-SXS67, IN-RZB20, IN-RZB21/RZD74
Immature turnip foliage	30	IN-E8S72 (35%), IN-WR791 (23%), IN-RZB20 (23%)	OXP and nonpolar metabolites, IN-RZB21/RZD74, IN-KJ552
	120	IN-WR791 (14%), IN-RZB20 (24%), IN-SXS67 (10%), IN-RZB21/RZD74 (10%)	IN-E8S72
	365	IN-E8S72 (15%), IN-WR791 (41%), IN-RZB20 (17%), IN-RZB21/RZD74 (11%)	IN-SXS67
Mature turnip foliage	30	IN-E8S72 (19%), IN-WR791 (27%), IN-RZB20 (18%), IN-RZB21/RZD74 (16%)	IN-SXS67, IN-KJ552, IN-RDG40, unknown compound eluting at *ca.* 19 min
	120	IN-E8S72 (12%), IN-WR791 (21%), IN-RZB20 (26%), IN-RZB21/RZD74 (11%)	IN-SXS67, IN-KJ552, unknown compound eluting at *ca.* 19 min
	365	IN-E8S72 (42%), IN-WR791 (29%), IN-RZB21/RZD74 (17%)	OXP and nonpolar metabolites, IN-SXS67, IN-RZB20, IN-KJ552
Metabolites Identified		**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Matrices	**PBI (days)**	**[Isoxazoline-5-^{14}C]**	**[Isoxazoline-5-^{14}C]**
Wheat forage	30	—	OXP and nonpolar metabolites
Wheat straw	30	OXP and nonpolar metabolites (11%)	IN-Q7H09, IN-RDG40, unknown compounds eluting at *ca.* 14 min, *ca.* 16 min, *ca.* 19 min
	120	OXP and nonpolar metabolites (10%)	IN-Q7H09, IN-RDG40, unknown compounds eluting at *ca.* 13 min, *ca.* 14 min, *ca.* 15 min, *ca.* 16 min, *ca.* 19 min
	365	Unknown compound eluting at *ca.* 15 min (12%)	Unknown compounds eluting at *ca.* 13 min, *ca.* 16 min, *ca.* 19 min

Turnip tubers	30	Unknown compound eluting at *ca.* 15 min (16%)	---

The primary metabolic pathways of oxathiapiprolin in rotational crops were cleavage between the piperidine and pyrazole rings, either in the crops or in the soil with metabolites translocated into crops, followed by further oxidation to form the pyrazole-containing polar metabolites, and subsequent glucose conjugation. Hydroxylation of oxathiapiprolin was also detected.

NATURE OF THE RESIDUE IN LAYING HEN	**PMRA Document Number: 2365178**

Two groups of laying hens (5 hens/group) were dosed orally with [pyrazole-5-^{14}C] or [thiazole-5-^{14}C]oxathiapiprolin by gelatin capsule at doses corresponding to 17.4-17.8 ppm in feed once daily for 14 days. Samples of excreta were collected daily. Samples of eggs were collected twice daily. The hens were euthanized 6 hours after administration of the final dose.

Matrices	**[Pyrazole-5-^{14}C]**		**[Thiazole-5-^{14}C]**	
	TRRs (ppm)	**% of Administered Dose**	**TRRs (ppm)**	**% of Administered Dose**
Excreta (Days 1-14; total)	--	97.94	--	91.89
Cagewash	--	2.42	--	2.93
Eggs (Days 1-14; total)	0.012	0.02	0.008	0.01
Partially formed eggs	0.031	0.01	0.020	<0.01
Liver	0.096	0.02	0.103	0.02
Muscle	0.003	<0.01	0.003	<0.02
Skin with fat	0.016	<0.01	0.011	<0.01
Abdominal fat	0.030	<0.01	0.024	<0.01

Metabolites identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**
Whole eggs	OXP (22%)	OXP (10%), IN-QFD61 (38%)	Hydroxy metabolites, IN-Q7D41	IN-RDG40/Q7H09, IN-Q7D41
Liver	IN-QFD61 (10%+34%)	IN-RAB06 (14%), IN-QFD61 (10%+38%)	OXP, IN-RAB06, IN-RDG40/Q7H09	OXP, IN-RDG40/Q7H09
Abdominal fat	OXP (28%), IN-RDG40/Q7H09 (15%)	OXP (66%)	IN-Q7D41	--
Skin with fat	OXP (22%), IN-RDG40/Q7H09 (33%)	OXP (37%), IN-RDG40/Q7H09 (25%), IN-Q7D41 (10%)	IN-Q7D41	--

The primary metabolic pathways of oxathiapiprolin in poultry were hydroxylation in various positions of the molecule, and further oxidation to carboxylic acid. The oxidative cleavage of isoxazoline and/or piperidine rings were also observed.

NATURE OF THE RESIDUE IN LACTATING GOAT	**PMRA Document Number: 2365176**

One lactating goat per radiolabel was dosed orally with [pyrazole-5-^{14}C] or [thiazole-5-^{14}C]oxathiapiprolin by gelatin capsule at doses corresponding to 14.2-14.3 ppm in feed once daily for 7 days. Samples of excreta were collected daily. Milk was collected twice daily. The goats were euthanized 12 hours after administration of the final dose.

Matrices	**[Pyrazole-5-^{14}C]**		**[Thiazole-5-^{14}C]**	
	TRRs (ppm)	**% of Administered Dose**	**TRRs (ppm)**	**% of Administered Dose**
Faeces	--	81.8	--	79.4
Urine	--	3.8	--	4.0
Cagewash	--	0.8	--	0.9
Bile	2.769	--	5.459	--
Milk (Days 1-7; total)	0.023	0.2	0.024	0.1
Liver	0.857	0.5	0.834	0.7
Kidney	0.087	<0.1	0.073	<0.1

Muscle	0.013	0.1	0.018	0.2
Omental fat	0.028	<0.1	0.029	0.1
Renal fat	0.026	<0.1	0.028	<0.1
Subcutaneous fat	0.025	0.1	0.026	0.1
GI contents	--	12.3	--	8.4
Metabolites identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**	**[Pyrazole-5-^{14}C]**	**[Thiazole-5-^{14}C]**
Milk	OXP (11%), IN-RAB06 (11%), unknown compounds eluting at 31.1 min (18%), 36.5 min (13%)	IN-RAB06 (11%), unknown compounds eluting at 30.2 min (13%), 36.4 min (10%)	IN-QFD61, IN-Q7D41, IN-RDG40/Q7H09	OXP, IN-QFD61, IN-Q7D41, IN-RDG40/Q7H09,
Liver	OXP (12%), IN-RDG40/Q7H09 (13%)	IN-RDG40/Q7H09 (11%)	IN-RAB06, IN-RLB67, IN-Q7D41, unknown compounds eluting at 22.4-57.4 min (6 peaks)	OXP, IN-RAB06, IN-RLB67, IN-Q7D41, IN-QFD61, unknown compounds eluting at 15.5-54.5 min (4 peaks)
Kidney	OXP (13%), IN-RDG40/Q7H09 (16%), IN-E8S72 (24%)	OXP (14%), IN-RDG40/Q7H09 (21%)	IN-RAB06	IN-RAB06
Muscle	OXP (43%), IN-RDG40/Q7H09 (30%)	OXP (27%), IN-RDG40/Q7H09 (28%)	--	IN-Q7D41
Omental fat	OXP (46%), IN-RDG40/Q7H09 (25%), IN-Q7D41 (15%)	OXP (54%), IN-RDG40/Q7H09 (14%), IN-Q7D41 (10%)	--	--
Renal fat	OXP (36%), IN-RDG40/Q7H09 (26%), IN-Q7D41 (12%)	OXP (49%), IN-RDG40/Q7H09 (24%), IN-Q7D41 (15%)	--	--
Subcutaneous fat	OXP (58%), IN-RDG40/Q7H09 (16%), IN-Q7D41 (11%)	OXP (48%), IN-RDG40/Q7H09 (13%)	--	IN-Q7D41

The primary metabolic pathways of oxathiapiprolin in ruminants were hydroxylation in various positions of the molecule, and further oxidation to carboxylic acid. The oxidative cleavage of isoxazoline and/or piperidine rings were also observed. Cleavage of the bond between pyrazole and bridge methylene carbon of IN-RAB06 resulted in formation of IN-E8S72.

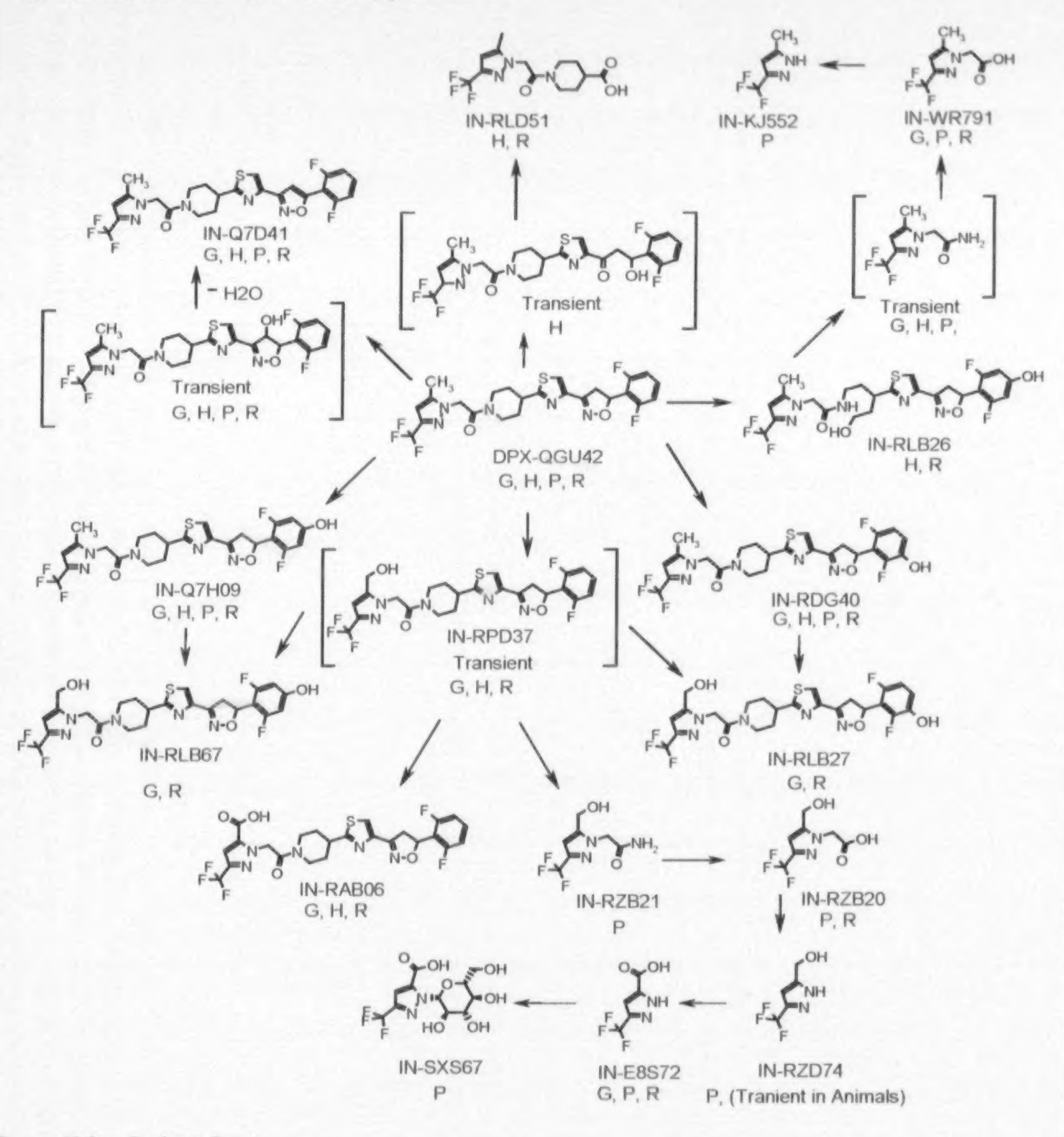
NATURE OF THE RESIDUE IN LACTATING GOAT – Metabolite IN-SXS67	**PMRA Document Number: 2364965**

A lactating goat was dosed orally with [pyrazole-5-^{14}C]IN-SXS67 by gelatin capsule at a dose corresponding to 18.95 ppm in feed once daily for 7 days. Samples of excreta were collected daily. Milk was collected twice daily. The goat was euthanized 6 hours after administration of the final dose.

Matrices	**[Pyrazole-5-^{14}C]**	
	TRRs (ppm)	**% of Administered Dose**
Feces	--	59.1
Urine	--	26.0
Cagewash	--	0.14
Bile	0.016	<0.1
Milk (Days 1-7; total)	0.002	<0.1
Liver	0.038	<0.1
Kidney	0.476	<0.1

Flank muscle	0.005	<0.1
Loin muscle	0.005	
Omental fat	0.002	<0.1
Renal fat	0.005	<0.1
Subcutaneous fat	0.006	<0.1
GI tract with contents	--	12.5
Metabolites identified	**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Radiolabel Position	**[Pyrazole-5-^{14}C]**	**[Pyrazole-5-^{14}C]**
Liver	IN-SXS67 (79%), IN-E8S72 (13%)	--
Kidney	IN-SXS67 (58%), IN-E8S72 (39%)	--
The metabolic fate of IN-SXS67, a plant metabolite of oxathiapiprolin, was investigated in ruminants. IN-SXS67 metabolised primarily to IN-E8S72. The total radioactive residues in the milk, muscle and fat were low.		

Proposed Metabolic Pathways for Oxathiapiprolin


IN-RLD51
H, R
IN-KJ552
P
IN-WR791
G, P, R
IN-Q7D41
G, H, P, R
- H2O
Transient
H
Transient
G, H, P,
Transient
G, H, P, R
DPX-QGU42
G, H, P, R
IN-RLB26
H, R
IN-Q7H09
G, H, P, R
IN-RPD37
Transient
G, H, R
IN-RDG40
G, H, P, R
IN-RLB67
G, R
IN-RLB27
G, R
IN-RAB06
G, H, R
IN-RZB21
P
IN-RZB20
P, R
IN-SXS67
P
IN-E8S72
G, P, R
IN-RZD74
P, (Tranient in Animals)

G: goat, H: hen, P: plants, R: rat

FREEZER STORAGE STABILITY	**PMRA Document Number: 2364992**

Plant matrices (tomatoes, potato tubers, dry bean seed, soybean seed, grapes, grape dry pomace, wheat forage, straw and grain): Residues of oxathiapiprolin and metabolites IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 are stable for up to 18 months when crop samples are stored frozen at -20±10°C.

CROP FIELD TRIALS & RESIDUE DECLINE ON POTATO	**PMRA Document Number: 2364953**

Field trials were conducted in 2012 in Canada and the United States, in NAFTA Growing Regions 1 (3 trials), 2 (1 trial), 3 (1 trial), 5 (5 trials), 9 (1 trial), 10 (1 trial), 11 (7 trials), 12 (1 trial) and 14 (2 trials) for a total of 22 trials. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 50 g a.i./ha/application for a seasonal application rate of 140-219 g a.i./ha. The applications were made at 5±1-day intervals with the last application occurring 4-5 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 14 days); since all oxathiapiprolin residues in/on potato tubers were <LOQ, decline behaviour could not be determined.

Metabolites: Residues of IN-E8S72 and IN-WR791 in/on potato tubers were <LOQ following four applications at a total rate of 140-219 g a.i./ha and a PHI of 4-5 days. Potato tuber samples were not analysed for the other metabolites.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min. #	Max. #	LAFT*	HAFT*	Median*	Mean*	SD*
Potato tubers	140-219	4-5	22	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	NA

Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON DRY BULB ONIONS	**PMRA Document Number: 2364949**

Field trials were conducted in 2011 and 2012 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 5/5B (5 trials), 6 (1 trial), 10 (3 trials) and 11 (2 trials) for a total of 12 trials. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 135-146 g a.i./ha. The applications were made at 5 day intervals with the last application occurring 0 or 4-6 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 14 days) and show that residues of oxathiapiprolin decreased in/on dry bulb onions with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on dry bulb onions were <LOQ following four applications at a total rate of 135-146 g a.i./ha and a 0-day PHI.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.#	Max.#	LAFT*	HAFT*	Median*	Mean*	SD*
Dry bulb onion	135-146	0	12	<0.01	0.026	0.01	0.026	0.011	0.014	0.005

Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON GREEN ONIONS	**PMRA Document Number: 2364949**

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 5/5B (2 trials), 6 (1 trial) and 10 (2 trials) for a total of 5 trials. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 138-150 g a.i./ha. The applications were made at 5-day intervals with the last application occurring 0 or 4-6 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 14 days) and show that residues of oxathiapiprolin decreased in/on green onions with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on green onions were <LOQ following four applications at a total rate of 138-150 g a.i./ha and a 0-day PHI.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.[#]	Max.[#]	LAFT*	HAFT*	Median*	Mean*	SD*
Green onion (whole plant)	138-150	0	5	0.38	0.86	0.40	0.85	0.57	0.58	0.18

[#] Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON LETTUCE | **PMRA Document Number: 2364884 and 2364927**

Foliar Application:

Field trials were conducted in 2011 and 2012 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 2 (2 trials), 3 (1 trial), 5/5B (2 trials), 9 (1 trial), 10 (3 trials) and 11 (1 trial) for a total of 11 trials on head lettuce, and in NAFTA Growing Regions 2 (1 trial), 3 (1 trial), 5/5B (4 trials), 9 (1 trial), 10 (3 trials) and 11 (1 trial) for a total of 11 trials on leaf lettuce. DPX-QGU42 100 g/L OD formulation was applied three times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 140-149 g a.i./ha. The applications were made at 3±1-day intervals with the last application occurring 0 or 3 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 23/27 days) and show that residues of oxathiapiprolin decreased in/on head and leaf lettuce with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on head and leaf lettuce were <LOQ following three applications at a total rate of 140-149 g a.i./ha and a 0-day PHI.

Soil Application:

Field trials were conducted in 2011 and 2012 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 2 (2 trials), 3 (1 trial), 5/5B (2 trials), 9 (1 trial), 10 (3 trials) and 11 (1 trial) for a total of 11 trials on head lettuce, and in NAFTA Growing Regions 2 (1 trial), 3 (1 trial), 5/5B (4 trials), 9 (1 trial), 10 (3 trials) and 11 (1 trial) for a total of 11 trials on leaf lettuce. DPX-QGU42 100 g/L OD or 200 g/L SC formulation was applied two times as drip/drench/shank/basal in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 545-578 g a.i./ha. The applications were made at 7±1-day intervals with the last application occurring 0 or 3 days before harvest. Adjuvants were not included.

Residue decline: Data were collected (0 to 23/27 days) and show that residues of oxathiapiprolin decreased in/on head and leaf lettuce with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on head and leaf lettuce were <LOQ following two soil applications at a total rate of 545-578 g a.i./ha and a 0-day PHI.

Additional Soil Application Trials:

Three field trials were conducted in 2011/2012 in Canada and the United States in NAFTA Growing Regions 1, 5 and 10 on leaf lettuce. DPX-QGU42 200 g/L SC formulation was applied two times as drip/drench/shank/basal in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 556-560 g a.i./ha. The applications were made at 7±1-day intervals with the last application occurring between 0 and 70 days before harvest. Adjuvants were not included.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.[#]	Max.[#]	LAFT*	HAFT*	Median*	Mean*	SD*
Head lettuce with wrapper leaves	140-149 (foliar)	0	11	0.20	1.5	0.23	1.4	0.57	0.67	0.40
	560-578 (soil)	0	11	<0.01	0.47	<0.01	0.43	0.01	0.08	0.16
Leaf lettuce plant without roots	140-148 (foliar)	0	11	0.41	3.1	0.53	3.0	1.8	1.5	0.78
	545-578 (soil)	0	11	<0.01	0.38	<0.01	0.37	0.01	0.06	0.11
Leaf lettuce	556-560 (soil)	0	3	<0.01	3.7	<0.01	2.9	0.01	0.97	1.7

[#] Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the

LOQ.
n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON SPINACH | **PMRA Document Number: 2364889**

Foliar Application:

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 2 (1 trial), 5/5B (2 trials), 6 (2 trials), 9 (1 trial), 10 (2 trials) and 12 (1 trial) for a total of 10 trials. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 136-145 g a.i./ha. The applications were made at 3-day intervals with the last application occurring 0 or 3-4 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 30 days) and show that residues of oxathiapiprolin decreased in/on spinach leaves with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on spinach leaves were <LOQ following four applications at a total rate of 136-145 g a.i./ha and a 0-day PHI.

Soil Application:

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 2 (1 trial), 5/5B (2 trials), 6 (2 trials), 9 (1 trial), 10 (2 trials) and 12 (1 trial) for a total of 10 trials. DPX-QGU42 200 g/L SC formulation was applied two times as drip/drench/shank/basal in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 549-575 g a.i./ha. The applications were made at 7-day intervals with the last application occurring 0 or 3 days before harvest. Adjuvants were not included.

Residue decline: Data were collected (0 to 30 days) and show that residues of oxathiapiprolin decreased in/on spinach leaves with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on spinach leaves were <LOQ following two soil applications at a total rate of 549-575 g a.i./ha and a 0-day PHI.

Commodity	**Total Application Rate (g a.i./ha)**	**PHI (days)**	**Oxathiapiprolin Residue Levels (ppm)**							
			n	**Min.**[#]	**Max.**[#]	**LAFT***	**HAFT***	**Median***	**Mean***	**SD***
Spinach leaves	136-145 (foliar)	0	10	1.3	7.0	1.4	6.5	3.4	3.7	1.9
	549-575 (soil)	0	10	<0.01	2.1	<0.01	2.1	0.11	0.73	0.90

[#] Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON BROCCOLI | **PMRA Document Number: 2364895**

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 5 (1 trial) and 10 (3 trials) for a total of 5 trials. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 139-142 g a.i./ha. The applications were made at 5±1-day intervals with the last application occurring 0 or 5 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 29 days) and show that residues of oxathiapiprolin decreased in/on broccoli with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on broccoli were <LOQ following four applications at a total rate of 139-142 g a.i./ha and a 0-day PHI.

Commodity	**Total Application Rate (g a.i./ha)**	**PHI (days)**	**Oxathiapiprolin Residue Levels (ppm)**							
			n	**Min.**[#]	**Max.**[#]	**LAFT***	**HAFT***	**Median***	**Mean***	**SD***
Broccoli	139-142	0	5	0.056	0.84	0.066	0.81	0.21	0.297	0.294

[#] Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON CABBAGE	**PMRA Document Number: 2364895**

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 1 (2 trials), 2 (1 trial), 3 (1 trial), 5 (3 trials), 6 (1 trial), 8 (1 trial) and 10 (1 trial) for a total of 10 trials. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 137-143 g a.i./ha. The applications were made at 5±1-day intervals with the last application occurring 0 or 4-6 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 30 days) and show that residues of oxathiapiprolin decreased in/on cabbage with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on cabbage were <LOQ following four applications at a total rate of 137-143 g a.i./ha and a 0-day PHI.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.°	Max.	LAFT*	HAFT*	Median*	Mean*	SD*
Cabbage	137-143	0	10	0.043	0.46	0.044	0.42	0.14	0.178	0.129

° Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON CAULIFLOWER	**PMRA Document Number: 2364895**

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions (2 trials), 10 (2 trials) and 12 (1 trial) for a total of 5 trials. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 139-143 g a.i./ha. The applications were made at 5±1-day intervals with the last application occurring 0 or 5 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 and 5 days). Residues of oxathiapiprolin decreased in/on cauliflower with increasing PHIs; however, there is limited information since the data were collected at only two time points.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on cauliflower were <LOQ following four applications at a total rate of 139-143 g a.i./ha and a 0-day PHI.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.°	Max.°	LAFT*	HAFT*	Median*	Mean*	SD*
Cauliflower	139-143	0	5	0.073	0.17	0.077	0.14	0.082	0.094	0.026

° Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON TOMATOES	**PMRA Document Number: 2364946 and 2364927**

Foliar Application:

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions (1 trial), 2 (1 trial), 3 (2 trials), 5 (8 trials) and 10 (7 trials) for a total of 19 trials (9 trials on small varieties and 10 on standard size varieties). DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 136–144 g a.i./ha. The applications were made at 5±1-day intervals with the last application occurring 0 or 5 days before harvest. An adjuvant was included in all spray mixes.

Greenhouse trials were conducted in NAFTA Growing Regions 1 (2 trials) and 5 (2 trials) for a total of 4 trials (2 trials each on small and standard size varieties). DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 140-147 g a.i./ha. The applications were made at 5±1-day intervals with the last application occurring 0 days before harvest. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 30 days) and show that residues of oxathiapiprolin decreased in/on tomatoes with increasing PHIs. In the greenhouse trials, residues of oxathiapiprolin increased at PHIs of 5 and 10 days, after which they began to decline.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on tomatoes were <LOQ following four applications at a total rate of 136-147 g a.i./ha and a 0-day PHI.

Soil Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 2 (1 trial), 3 (2 trials), 5 (8 trials) and 10 (7 trials) for a total of 19 trials. DPX-QGU42 100 g/L OD or 200 g/L SC formulation was applied two times as drip/drench/shank/basal in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 554-611 g a.i./ha. The applications were made at 7±1-day intervals with the last application occurring 0 or 5 days before harvest. Adjuvants were not included.
Residue decline: Data were collected (0 to 30 days) and show that residues of oxathiapiprolin decreased in/on tomatoes with increasing PHIs.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on tomatoes were <LOQ following two soil applications at a total rate of 554-611 g a.i./ha and and a 0-day PHI.

Additional Soil Application Trials:
Three field trials were conducted in 2011/2012 in Canada and the United States in NAFTA Growing Regions 1, 5 and 10 on tomatoes. DPX-QGU42 200 g/L SC formulation was applied two times as drip/drench/shank/basal in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 560-566 g a.i./ha. The applications were made at 7±1-day intervals with the last application occurring between 0 and 84 days before harvest. Adjuvants were not included.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.¹	Max.¹	LAFT*	HAFT*	Median*	Mean*	SD*
Tomato fruit (Field)	136-144 (foliar)	0	19	<0.01	0.35	<0.01	0.31	0.039	0.065	0.07
	554-611 (soil)	0	19	<0.01	0.44	<0.01	0.24	0.01	0.02	0.05
Tomato fruit (Greenhouse)	140-147 (foliar)	0	4	<0.01	0.037	<0.01	0.035	0.015	0.019	0.01
		5	4	<0.01	0.073	0.011	0.064	0.021	0.029	0.03
Field tomato	560-566 (soil)	0	3	<0.01	0.070	<0.01	0.054	0.01	0.025	0.025

¹ Values based on total number of samples.
* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON PEPPERS	PMRA Document Number: 2364530

Foliar Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 2 (2 trials), 3 (1 trial), 5 (4 trials), 6 (1 trial) and 10 (2 trials) for a total of 10 trials on bell peppers, and in NAFTA Growing Regions 2 (1 trial), 3 (1 trial), 5 (2 trials) and 9 (2 trials) for a total of 6 trials on nonbell peppers. DPX-QGU42 100 g/L OD formulation was applied three times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 140-156 g a.i./ha. The applications were made at 3±1-day intervals with the last application occurring 0 or 4-6 days before harvest. An adjuvant was included in all spray mixes.
Greenhouse trials were conducted in NAFTA Growing Regions 2 (1 trial) and 10 (1 trial) for a total of 2 trials on bell peppers. DPX-QGU42 100 g/L OD formulation was applied three times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 138-142 g a.i./ha. The applications were made at 2-3 day intervals with the last application occurring 0 or 4 days before harvest. An adjuvant was included in all spray mixes.
Residue decline: Data were collected (0 to 30/37 days) and show that residues of oxathiapiprolin decreased in/on nonbell and bell peppers with increasing PHIs. In the greenhouse trials, residues of oxathiapiprolin increased in one bell pepper trial, and declined in the other, at PHIs of 4 days.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on nonbell and bell peppers were ≤LOQ following three applications at a total rate of 140-156 g a.i./ha and a 0-day PHI.

Soil Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 2 (2 trials), 3 (1 trial), 5 (4 trials), 6 (1 trial) and 10 (2 trials) for a total of 10 trials on bell peppers, and in NAFTA Growing Regions 2 (1 trial), 3 (1 trial), 5

(2 trials) and 9 (2 trials) for a total of 6 trials on nonbell peppers. DPX-QGU42 100 g/L OD or 200 g/L SC formulation was applied two times as drip/drench/shank/basal in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 546-667 g a.i./ha. The applications were made at 7±1-day intervals with the last application occurring 0 days before harvest. Adjuvants were not included.
Residue decline: Data were collected (0 to 27/28 days) and show that residues of oxathiapiprolin decreased in/on bell and nonbell peppers with increasing PHIs.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on nonbell and bell peppers were <LOQ following two soil applications at a total rate of 546-667 g a.i./ha and and a 0-day PHI.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.[1]	Max.[1]	LAFT*	HAFT*	Median*	Mean*	SD*
Bell pepper (Field)	140-146 (foliar)	0	10	0.015	0.15	0.016	0.119	0.052	0.059	0.029
	558-667 (soil)	0	10	<0.01	0.029	<0.01	0.017	0.01	0.011	0.002
Nonbell pepper (Field)	142-156 (foliar)	0	6	0.039	0.15	0.038	0.128	0.057	0.063	0.037
	546-574 (soil)	0	6	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	N/A
Bell pepper (Greenhouse)	138-142 (foliar)	0	2	0.027	0.14	0.027	0.12	0.078	0.078	N/A
		8	2	0.051	0.070	0.058	0.061	0.060	0.060	N/A

[1] Values based on total number of samples.
* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON CUCUMBERS	PMRA Document Number: 2364899

Foliar Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 2 (4 trials), 3 (1 trial), 5 (4 trials), 6 (2 trials) and 12 (1 trial) for a total of 12 trials on cucumbers. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 136-145 g a.i./ha. The applications were made at 5-day intervals with the last application occurring 0 or 3 days before harvest. An adjuvant was included in all spray mixes.
A total of four greenhouse trials were conducted on cucumbers. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 140-142 g a.i./ha. The applications were made at 5-day intervals with the last application occurring 0 or 3 days before harvest. An adjuvant was included in all spray mixes.
Residue decline: Data were collected (0 to 30 days) and show that residues of oxathiapiprolin decreased in/on cucumbers with increasing PHIs, both in the greenhouse and in the field trials.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on cucumbers were <LOQ following four applications at a total rate of 136-145 g a.i./ha and a 0-day PHI.

Soil Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 2 (3 trials), 3 (1 trial), 5 (4 trials), 6 (2 trials) and 12 (1 trial) for a total of 11 trials on cucumbers. DPX-QGU42 100 g/L OD or 200 g/L SC formulation was applied two times as drip/drench/shank/basal in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 518-578 g a.i./ha. The applications were made at 7±1-day intervals with the last application occurring 0 or 3 days before harvest. Adjuvants were not included.
Residue decline: Data were collected (0 to 29 days) and show that, after an initial increase for up to 3 days, residues of oxathiapiprolin decreased in/on cucumbers with increasing PHIs.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on cucumbers were <LOQ following two soil applications at a total rate of 518-578 g a.i./ha and and a 0-day PHI.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.*	Max.*	LAFT#	HAFT#	Median#	Mean#	SD#
Cucumbers (Field)	139-147 (foliar)	0	17	<0.01	0.096	<0.01	0.090	0.026	0.030	0.032
	558-578 (soil)	0	16	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	N/A
Cucumbers (Greenhouse)	140-147 (foliar)	0	8	0.023	0.087	0.022	0.068	0.040	0.037	0.03
		3	8	0.016	0.038	0.038	[illegible]	0.020	0.023	0.007

* Values based on total number of samples.
# Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON SUMMER SQUASH	PMRA Document Number: [illegible] and [illegible]

Foliar Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 2 (2 trials), 3 (1 trial), 5/5A (4 trials), 10 (1 trial) and 12 (1 trial) for a total of 10 trials on summer squash. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 138-149 g a.i./ha. The applications were made at 7-day intervals with the last application occurring 0 or 1 days before harvest. An adjuvant was included in all spray mixes.
Residue decline: Data were collected (0 to 28 days) and show that residues of oxathiapiprolin decreased in/on summer squash with increasing PHIs.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on summer squash were <LOQ following four applications at a total rate of 138-149 g a.i./ha and a 0-day PHI.

Soil Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 1 (1 trial), 2 (2 trials), 3 (1 trial), 5 (4 trials), 10 (1 trial) and 12 (1 trial) for a total of 10 trials on summer squash. DPX-QGU42 100 g/L OD or 200 g/L SC formulation was applied two times as drip/drench/shank/band in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 557-578 g a.i./ha. The applications were made at 7-day intervals with the last application occurring 0 or 3 days before harvest. Adjuvants were not included.
Residue decline: Data were collected (0 to 30 days) and show that residues of oxathiapiprolin decreased in/on summer squash with increasing preharvest intervals (PHIs).
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on summer squash were <LOQ following two soil applications at a total rate of 557-578 g a.i./ha and and a 0-day PHI.

Additional Soil Application Trials:
Three field trials were conducted in 2011/2012 in Canada and the United States in NAFTA Growing Regions 1, 5 and 10 on summer squash. DPX-QGU42 200 g/L SC formulation was applied two times as drip/drench/shank/band in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 560-566 g a.i./ha. The applications were made at 7±1-day intervals with the last application occurring between 0 and 44 days before harvest. Adjuvants were not included.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.*	Max.*	LAFT#	HAFT#	Median#	Mean#	SD#
Summer squash (Field)	138-149 (foliar)	0	10	<0.01	0.17	0.01	0.130	0.052	0.061	0.053
	557-578 (soil)	0	10	<0.01	0.062	<0.01	0.027	0.010	0.015	0.009
Summer squash	560-566 (soil)	0	3	<0.01	0.015	<0.01	0.015	0.01	0.011	0.002

* Values based on total number of samples.
# Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON CANTALOUPE	**PMRA Document Number: 2364906**

Foliar Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 2 (3 trials), 5/5B (4 trials), 6 (2 trials) and 10 (3 trials) for a total of 12 trials on cantaloupe. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 35 g a.i./ha/application for a seasonal application rate of 138-146 g a.i./ha. The applications were made at 3-day intervals with the last application occurring 0 or 3 days before harvest. An adjuvant was included in all spray mixes.
Residue decline: Data were collected (0 to 28 days) and show that residues of oxathiapiprolin decreased in/on cantaloupe with increasing PHIs.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on cantaloupe were <LOQ following four applications at a total rate of 138-146 g a.i./ha and a 0-day PHI.

Soil Application:
Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 2 (3 trials), 5/5B (4 trials), 6 (2 trials) and 10 (3 trials) for a total of 12 trials on cantaloupe. DPX-QGU42 100 g/L OD or 200 g/L SC formulation was applied two times as drip/drench/shank/basal in-season applications at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 542-578 g a.i./ha. The applications were made at 7±1-day intervals with the last application occurring 0 days before harvest. Adjuvants were not included.
Residue decline: Data were collected (0 to 27 days) and show that residues of oxathiapiprolin decreased in/on cantaloupe with increasing PHIs.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on cantaloupe were <LOQ following two soil applications at a total rate of 542-578 g a.i./ha and and a 0-day PHI.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.†	Max.†	LAFT*	HAFT*	Median*	Mean*	SD*
Cantaloupe, whole fruit (Field)	138-146 (foliar)	0	12	0.012	0.13	0.014	0.120	0.045	0.054	0.033
	542-578 (soil)	0	12	<0.01	0.034	<0.01	0.025	0.010	0.012	0.004

† Values based on total number of samples.
* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON SUCCULENT PEAS	**PMRA Document Number: 2364877**

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Regions 1A (1 trial), 2 (1 trial), 5B (2 trials), 11 (1 trial), and 12 (1 trial) for a total of 6 trials on shelled peas, and in NAFTA Growing Regions 1 (1 trial), 2 (1 trial), 5/5B (3 trials) and 11 (1 trial) for a total of 6 trials on edible podded peas. DPX-QGU42 100 g/L OD formulation was applied four times as foliar broadcast sprays at a rate of approximately 50 g a.i./ha/application for a seasonal application rate of 140-153 g a.i./ha. The applications were made at 5±1-day intervals with the last application occurring 0 days before harvest. An adjuvant was included in all spray mixes.
Residue decline: Data were collected (0 to 14 days) and show that residues of oxathiapiprolin decreased in/on whole peas with increasing PHIs.
Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on succulent peas were <LOQ following four applications at a total rate of 140-153 g a.i./ha and a 0-day PHI, except one trial on whole peas where IN-WR791 residues were observed (0.012-0.013 ppm).

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.[#]	Max.[#]	LAFT*	HAFT*	Median*	Mean*	SD*
Whole peas (edible podded)	142-153	0	6	0.20	0.55	0.20	0.55	0.29	0.32	0.12
Shelled seed (succulent shelled)	140-153	0	6	<0.01	0.029	<0.01	0.026	0.011	0.016	0.008

[#] Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

CROP FIELD TRIALS & RESIDUE DECLINE ON GINSENG **PMRA Document Number: 2364875**

Field trials were conducted in 2011 in Canada and the United States, in NAFTA Growing Region 5 (4 trials). DPX-QGU42 100 g/L OD formulation was applied two times as foliar broadcast sprays at a rate of approximately 280 g a.i./ha/application for a seasonal application rate of 548-571 g a.i./ha. The applications were made at 15-day intervals with the last application occurring 13-14 days before harvest. At two sites, a second set of two applications were made 56-85 days later, for a total application rate of 1102-1125 g a.i./ha. Samples at these sites were also collected at PHIs of 13-14 days. An adjuvant was included in all spray mixes.

Residue decline: Data were collected (0 to 20 days), and showed an increase in residues of oxathiapiprolin in/on ginseng with increasing PHIs.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 in/on ginseng were <LOQ a PHI of 13-14 days following two applications at a total rate of 548-571 g a.i./ha.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residue Levels (ppm)							
			n	Min.[#]	Max.[#]	LAFT*	HAFT*	Median*	Mean*	SD*
Ginseng roots, dried	548-571	13-14	4	0.025	0.058	0.042	0.049	0.044	0.045	0.003
	1102-1125	13-14	2	0.064	0.15	0.072	0.140	0.106	0.106	NA

[#] Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

RESIDUE DATA IN ROTATIONAL CROPS **PMRA Document Number: 2364840 and 2364838**

Three trials (two each for radish, cereals and soybeans) were conducted during the 2011/2012 growing seasons in NAFTA Growing Regions 1 (1 trial) and 5 (2 trials). DPX-QGU42 100 g/L OD formulation was applied to bare soil two times at a rate of either 140 or 280 g a.i./ha/application for a seasonal application rate of 275-282 or 544-565 g a.i./ha. The applications were made at 7-day intervals. Adjuvants were not included. The rotational crops were subsequently planted in treated soil at plantback intervals (PBIs) of 7-30, 60-120 and 300-365 days.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-RZB20, IN-RZD74 and IN-WR791 in/on all rotational crop commodities at all PBIs were <LOQ following two soil applications at a total rate of 275-282 or 544-565 g a.i./ha.

Commodity	Total Application Rate (g a.i./ha)	PBI (days)	Residue Levels (ppm)			
			n	Oxathiapiprolin	IN-E8S72	IN-SXS67
Radish roots	275-282	8-17	2	<LOQ	<LOQ	<LOQ
		336-359	2	<LOQ	<LOQ	<LOQ
Radish tops		8-17	2	<LOQ	<LOQ	<LOQ
		336-359	2	<LOQ	<LOQ	<LOQ
Cereal forage	275-282	8-15	2	<LOQ	<LOQ	<LOQ-0.037
		120-140	2	<LOQ	<LOQ	<LOQ-0.010
		334-344	2	<LOQ	<LOQ	<LOQ
Cereal hay		8-15	2	<LOQ	<LOQ-0.014	<LOQ-0.080
		120-140	2	<LOQ	<LOQ	0.011-0.022
		334-344	2	<LOQ	<LOQ	<LOQ-0.017
Cereal grain		120-140	2	<LOQ	<LOQ	<LOQ
		334-344	2	<LOQ	<LOQ	<LOQ
Cereal straw		8-15	2	<LOQ	<LOQ	<LOQ
		120-140	2	<LOQ	<LOQ-0.011	<LOQ-0.016
		334-344	2	<LOQ	<LOQ	<LOQ
Soybean forage	279-282	9-21	2	<LOQ	0.022	<LOQ
		63-77	2	<LOQ-0.036	<LOQ-0.019	<LOQ
		319-359	2	<LOQ	<LOQ	<LOQ
Soybean hay		9-21	2	<LOQ	0.032-0.10	0.019-0.021
		63-77	2	<LOQ	<LOQ-0.037	<LOQ-0.017
		319-359	2	<LOQ	<LOQ	<LOQ
Soybean immature bean with pods		9-21	2	<LOQ	<LOQ-0.012	<LOQ-0.039
		63-77	2	<LOQ	<LOQ-0.012	<LOQ-0.013
		319-359	2	<LOQ	<LOQ	<LOQ
Soybean mature seed		9-21	2	<LOQ	**<LOQ-0.025**	**0.010-0.057**
		63-77	2	<LOQ	**<LOQ-0.023**	**<LOQ-0.015**
		319-359	2	<LOQ	**<LOQ-0.010**	**<LOQ-0.011**

Commodity	Total Application Rate (g a.i./ha)	PBI (days)	Residue Levels (ppm)			
			n	Oxathiapiprolin	IN-E8S72	IN-SXS67
Radish roots	544-565	8-17	2	<LOQ	<LOQ	<LOQ
		75-103	2	<LOQ	<LOQ	<LOQ
		336-359	2	<LOQ	<LOQ	<LOQ
Radish tops		8-17	2	<LOQ	0.011	<LOQ
		75-103	2	<LOQ	<LOQ	<LOQ
		336-359	2	<LOQ	<LOQ-0.022	<LOQ
Cereal forage	544-565	8-15	2	<LOQ	<LOQ	0.018-0.061
		120-140	2	<LOQ	<LOQ-0.019	0.015-0.035
		334-344	2	<LOQ	<LOQ	<LOQ-0.048
Cereal hay		8-15	2	<LOQ	<LOQ-0.014	0.012-0.17
		120-140	2	<LOQ	<LOQ-0.016	0.030-0.064
		334-344	2	<LOQ	<LOQ	<LOQ-0.10
Cereal grain		8-15	2	<LOQ	<LOQ	<LOQ
		120-140	2	<LOQ	<LOQ	<LOQ
		334-344	2	<LOQ	<LOQ	<LOQ
Cereal straw		8-15	2	<LOQ	0.011-0.015	0.013-0.023
		120-140	2	<LOQ	<LOQ-0.025	<LOQ-0.043
		334-344	2	<LOQ	<LOQ-0.010	<LOQ-0.015
Soybean forage	555-565	9-21	2	<LOQ-0.011	0.058-0.067	0.012-0.019
		63-77	2	<LOQ-0.064	<LOQ-0.050	<LOQ-0.017
		319-359	2	<LOQ	<LOQ-0.017	<LOQ
Soybean hay		9-21	2	<LOQ-0.012	0.066-0.25	0.078
		63-77	2	<LOQ	0.015-0.077	0.010-0.068
		319-359	2	<LOQ	<LOQ-0.015	<LOQ-0.028
Soybean immature bean with pods		9-21	2	<LOQ	0.021-0.028	0.024-0.050
		63-77	2	<LOQ	<LOQ-0.019	<LOQ-0.016
		319-359	2	<LOQ	<LOQ-0.026	<LOQ
Soybean mature seed		9-21	2	<LOQ	0.029-0.048	0.036-0.083
		63-77	2	<LOQ	<LOQ-0.019	<LOQ-0.014
		319-359	2	<LOQ	<LOQ-0.028	<LOQ-0.033

n = number of field trials.

Thirty-two trials (one for sorghum; two for mustard greens; three each for strawberries, lettuce, celery, soybeans and canola; four for sugar beets, five each for corn and wheat) were conducted during the 2012 growing seasons in NAFTA Growing Regions 2 (2 trials), 3 (1 trial), 4 (1 trial), 5 (12 trials), 7 (5 trials), 8 (1 trial), 10 (7 trials) and 14 (3 trials). DPX-QGU42 100 g/L OD formulation (or 200 g/L SC, in one wheat trial only) was applied to bare soil two times at a rate of 140 g a.i./ha/application for a seasonal application rate of 272-287 g a.i./ha. The applications were made at 7-day intervals. An adjuvant was included in all spray mixes. The rotational crops were subsequently planted in treated soil at plantback intervals (PBIs) of 5-10 days.

Metabolites: Residues of IN-Q7H09, IN-RDG40, IN-RZB20, IN-RZD74 and IN-WR791 (except an average residue of 0.012 ppm in wheat hay) in/on all rotational crop commodities at all PBIs were <LOQ following two soil applications at a total rate of 272-287 g a.i./ha.

Commodity	**Total Application Rate (g a.i./ha)**	**PBI (days)**	**Residue Levels (ppm)**			
			n	**Oxathiapiprolin**	**IN-E8S72**	**IN-SXS67**
Strawberries	281-283	5-8	3	<LOQ	<LOQ-0.022	<LOQ
Sugar beet tops	277-283	5-7	4	<LOQ	<LOQ	<LOQ-0.039
Leaf lettuce immature leaves	280-286	6-10	3	<LOQ	<LOQ	<LOQ
Leaf lettuce mature leaves			3	<LOQ	<LOQ	<LOQ
Celery stalk	278-286	5-6	3	<LOQ	<LOQ	<LOQ
Mustard green leaves	280-282	7-8	2	<LOQ	0.015-0.025	<LOQ
Soybean forage	281-285	6-7	3	<LOQ	<LOQ-0.016	<LOQ-0.023
Soybean hay		6-7	3	<LOQ-0.010	0.013-0.15	0.0.18-0.057
Soybean immature seeds		6-7	3	<LOQ	<LOQ-0.023	<LOQ-0.025
Soybean immature pods		6-7	3	<LOQ	<LOQ	<LOQ-0.021
Soybean mature seeds		6-7	3	<LOQ	<LOQ-0.047	0.011-0.045
Corn forage	272-283	5-7	5	<LOQ	<LOQ	<LOQ-0.011
Sweet Corn K+CWHR		5-7	5	<LOQ	<LOQ	<LOQ
Corn stover		5-7	5	<LOQ	<LOQ	<LOQ
Sorghum forage	272-283	5-7	1	<LOQ	<LOQ	<LOQ
Sorghum stover		5-7	1	<LOQ	<LOQ	<LOQ
Wheat forage	279-287	5-9	5	<LOQ	<LOQ-0.08	0.018-0.31
Wheat hay			5	<LOQ	<LOQ-0.22	0.030-1.0
Wheat straw			5	<LOQ-0.011	<LOQ-0.099	0.020-0.20
Canola seed	281-284	5-9	3	<LOQ	<LOQ	<LOQ

n = number of field trials.

Based on the results of the confined crop rotation studies, field accumulation studies, and the toxicological profile of the active ingredient, plantback intervals are not required for the end-use products of oxathiapiprolin.

PROCESSED FOOD AND FEED - POTATO	**PMRA Document Number: 2364867**
Test Site	Three trials in NAFTA Growing Regions 1, 5 and 11
Treatment/Rate	Seed-piece treatment or in-furrow at plant at 1400 g ai/ha + Early foliar broadcast at 1400 g ai/ha + 4x foliar broadcast at 175 g ai/ha/application with RTIs of 5 days
Total rate	3500 g ai/ha
Formulation	200 g/L SC (seed piece/in-furrow and early foliar broadcast); 100 g/L OD (foliar broadcast applications)
Preharvest interval	5 days
Processed Commodity	**Median Processing Factor for Oxathiapiprolin Residues**
Washed tubers	0.1x
Culls	0.1x
Steam waste	1.2x
Dried flakes	<0.1x
Potato chips	<0.1x

PROCESSED FOOD AND FEED - TOMATO	**PMRA Document Number: 2364862**
Test Site	Three trials in NAFTA Growing Regions 1, 5 and 10
Treatment/Rate	2x soil-directed/base of plant at 280 g ai/ha + 4x foliar broadcast at 175 g ai/ha/application with RTIs of 5 days
Total rate	1260 g ai/ha
Formulation	200 g/L SC (soil-directed); 100 g/L OD (foliar broadcast applications)
Preharvest interval	0 day
Processed Commodity	**Median Processing Factor for Oxathiapiprolin Residues**
Washed tomatoes	0.5x
Sundried tomatoes	6.9x
Tomato juice	0.2x
Tomato paste	1.1x
Tomato puree	0.6x
Wet tomato pomace	13x

PROCESSED FOOD AND FEED - GRAPE	**PMRA Document Number: 2364869**
Test Site	Four trials in Europe (Germany, France, Spain)
Treatment/Rate	3x foliar broadcast at 50 g ai/ha/application, RTIs of 10±1 days (3 trials) or 3x foliar broadcast at 180 g ai/ha/application, RTIs of 9-12 days (1 trial)
Total rate	150 or 540 g ai/ha
Formulation	100 g/L OD
Preharvest interval	19-21 days
Processed Commodity	**Median Processing Factor for Oxathiapiprolin Residues**
Grape juice	0.2x
Raisins	1.5x
Wine	0.1x

LIVESTOCK FEEDING	**PMRA Document Number: 2365372**
Based on the residue and metabolism data submitted, and the use pattern of the end-use products, residues of oxathiapiprolin in/on animal commodities are not expected. Thus, livestock feeding studies are not required. MRLs on animal commodities, except poultry, will be recommended at the LOQ of the enforcement method for animal matrices.	

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops (lettuce, potato, grape)**	Oxathiapiprolin
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops** **Rotational crops**	Oxathiapiprolin Oxathiapiprolin
METABOLIC PROFILE IN DIVERSE CROPS (Foliar applications in lettuce, potato and grape, and soil applications in lettuce, potato and courgette)	Similar in crops investigated
ANIMAL STUDIES	
ANIMALS	**Ruminant and Poultry**
RESIDUE DEFINITION FOR ENFORCEMENT	Oxathiapiprolin
RESIDUE DEFINITION FOR RISK ASSESSMENT	Oxathiapiprolin
METABOLIC PROFILE IN ANIMALS (Goat, hen, rat)	Similar in animals investigated
FAT SOLUBLE RESIDUE	No

DIETARY RISK FROM FOOD AND WATER			
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Alone	**Food and Water**
Basic chronic non-cancer dietary exposure analysis **ADI = 4 mg/kg bw/day** **Estimated chronic drinking water concentration = 507 µg a.i./L**	**All infants < 1 year**	0.1	1.0
	Children 1–2 years	0.2	0.6
	Children 3–5 years	0.2	0.5
	Children 6–12 years	0.1	0.3
	Youth 13–19 years	0.1	0.3
	Adults 20–49 years	0.1	0.4
	Adults 50+ years	0.2	0.4
	Females 13–49 years	0.2	0.4
	Total population	0.1	0.4

Table 7 **Summary of fate and behaviour of oxathiapiprolin in the environment.**

Property	Test substance	DT_{50} [t_R] (days)	Major transformation products[a] (Max. %AR, [DAT])	Comments	PMRA Document Number
Abiotic transformation					
Phototransformation on soil	Oxathiapiprolin	82 – 87[b]	-	Not an important route	2364823
Phototransformation in air	Oxathiapiprolin	NA	NA	Oxathiapiprolin and its major transformation products have very low volatility. Phototransformation in air not conducted.	NA
Phototransformation in natural water	Oxathiapiprolin	45.2	IN-P3X26: 7.6 [15] in natural water (maximum 14.0 [15] in pH 7 buffered water)	Not an important route	2365250
Hydrolysis	Oxathiapiprolin	stable	-	Not an important route	2365253
Biotransformation					
Biotransformation in aerobic soil	Oxathiapiprolin	88.5 [231]	-	Moderately persistent	2364832
		162 [162]	IN-RDT31: 9.4 [120] IN-RAB06: 13.5 [120]	Moderately persistent	2365169
		134 [217]	-	Moderately persistent	2364830
		16.0 [176]	-	Slightly persistent	2364830
		59.2 [59.2]	-	Moderately persistent	2364830
		116 [116]	-	Moderately persistent	2364830
	IN-RAB06	84.3 [113]	-	Moderately persistent	2364803
		52.8 [75.3]	-	Moderately persistent	2364803
		75.6 [75.6]	-	Moderately persistent	2364803

Property	Test substance	DT_{50} [t_R] (days)	Major transformation products[a] (Max. %AR, [DAT])	Comments	PMRA Document Number
		38.8 [63.8]	-	Moderately persistent	2364803
		69.0 [69.0]	-	Moderately persistent	2364803
		201 [201]	-	Persistent	2364806
		8.4 [23.4]	-	Non-persistent	2364806
		10.3 [70.4]	-	Non-persistent	2364806
		3.3 [22.7]	-	Non-persistent	2364806
		99.3 [215]	-	Moderately persistent	2364806
	IN-RDT31	50.3 [81.4]	IN-E8S72: 13.7 [60]	Moderately persistent	2364813
		176 [2.8e+05]	-	Persistent	2364813
		50.5 [84.7]	IN-E8S72: 9.7 [60]	Moderately persistent	2364813
		813 [1290]	-	Persistent	2364813
		2113 [5.4e+03]	-	Persistent	2364813
	IN-E8S72	477 [477]	-	Persistent	2364811
		271 [271]	-	Persistent	2364811
		685 [1.29e+03]	-	Persistent	2364811
		328 [328]	-	Persistent	2364811

Property	Test substance	DT_{50} [t_{90}] (days)	Major transformation products[a] (Max. %AR, [DAT])	Comments	PMRA Document Number
		379 [379]	-	Persistent	2364811
	IN-QPS10	3.5 [83.1]	-	Non-persistent	2364815
		23.5 [74.8]	-	Slightly persistent	2364815
		364 [364]	-	Persistent	2364815
		262 [262]	-	Persistent	2364815
Biotransformation in anaerobic soil	Oxathiapiprolin	1505 [1505]	-	Persistent	2364825
Biotransformation in aerobic water systems	Oxathiapiprolin	Water: 5.5-13.5 [9.8 – 13.5] Whole system: 24.4 – 44.7 [44.7 – 229]	Whole system: IN-RYJ52: 16.0 [60] IN-S2K66: 8.7 [99] IN-Q7D41: 11.8 [99]	Slightly persistent in whole system	2364772
Biotransformation in anaerobic water systems	Oxathiapiprolin	Water: 25.2-33.0 [25.2-33.0] Whole system: 44.8 – 54.5 [44.8 – 54.5]	Whole system: IN-RYJ52: 29.9 [100] IN-S2K66: 11.4 [60] IN-QFD61: 20.2 [60] IN-S2K67: 13.6 [60]	Moderately persistent in whole system	2364770
		Water: 14.6-26.7 [14.6-26.7] Whole system: 48.9 – 56.4 [48.9 – 216]	Whole system: IN-RYJ52: 32.7 [100] IN-S2K66: 13.0 [100] IN-QFD61: 10.2 [60] IN-S2K67: 9.3 [100] IN-RSE01:	Moderately persistent in whole system	2364771

Property		Test substance	DT$_{50}$ [$_{90}$] (days)	Major transformation products[a] (Max. %AR, [DAT])	Comments	PMRA Document Number
				16.6 [30] 2,6-DFBA: 18.2 [100]		
Mobility						
Adsorption in soil K_d/K_{OC} (mL/g)		Oxathiapiprolin	54.5-557 / 4541-19214	5 soils (USA, Germany, France, Spain)	Immoile	2364778
			87.9 / 10987	1 US soil	Immoile	2364779
			160±195 / 8790±5590	Mean of 6 soils	Immoile	
		IN-E8S72	0.11±0.065 / 6.94±3.09	Mean of 5 soils (USA, Germany, France, Spain)	Very lgh	2364774
		IN-QPS10	121±124 / 6448±6522	Mean of 5 soils (USA, Germany, France, Spain)	Immoile	2364777
		IN-RAB06	13.8±6.8 / 820±359	Mean of 5 soils (USA, Germany, France, Spain)	Low	2364776
		IN-RDT31	36.3±22.6 / 1930±1199	Mean of 5 soils (USA, Germany, France, Spain)	Low	2364775
Volatilization		Not expected based on vapour pressure and Henrys law constant				
Field studies						
Field dissipation	Lyon, France	Oxathiapiprolin 100 g/L OD at 1×200 g a.i./ha (nominal)	5 [42]	-	Non-prsistent (Carryver: 6.5%)[c] (Max. \cpth: 15 cm)[d]	2364782
	Lentzke, Germany		39 [126]	IN-E8S72: 10.1 [300]	Slightl persistent (Carryver: 12%)[c] (Max. \cpth: 30 cm)[d]	2364783
	Cambridgeshire, UK		212 [212]	-	Persistnt (Carryver: 21%)[c] (Max. \cpth: 30 cm)[d]	2364780
	Sevilla, Spain		8 [104]	-	Non-prsistent (Carryver: 6%)[c] (Max. \cpth: 15 cm)[d]	2364781

Property		Test substance	DT_{50} [t_{90}] (days)	Major transformation products[a] (Max. %AR, [DAT])	Comments	PMRA Document Number
	New York, USA	Oxathiapiprolin 100 g/L OD @ 1×560 g a.i./ha (nominal)	8 [27]	-	Non-persistent (Carryover: 11%)[c] (Max. depth: 70 cm)[d]	2364788
	Texas, USA	Oxathiapiprolin 100 g/L OD @ 2×385 g a.i./ha (nominal)	9 [23]	IN-E8S72: 11.7 [52]	Non-persistent (Carryover: 3%)[c] (Max. depth: 15 cm)[d]	2364785
	Florida, USA (uncovered site)	Oxathiapiprolin 100 g/L OD @ 1×500 g a.i./ha (nominal)	34 [81]	-	Slightly persistent (Carryover: 8%)[c] (Max. depth: 15 cm)[d]	2364792
	California, USA	Oxathiapiprolin 100 g/L OD @ 1×560 g a.i./ha (nominal)	30 [52]	-	Slightly persistent (Carryover: 7%)[c] (Max. depth: 30 cm)[d]	2364790
	Manitoba, Canada		205 [205]	-	Persistent (Carryover: 39%)[c] (Max. depth: 30 cm)[d]	2364789
	British Columbia, Canada	Oxathiapiprolin 100 g/L OD @ 2×385 g a.i./ha (nominal)	169 [169]	-	Moderately persistent (Carryover: 20%)[c] (Max. depth: 70 cm)[d]	2364784

[a] Major transformation products are those occurring at greater than 10% applied radiation at any time, or near 10% and increasing at study conclusion.

[b] Environmental DT_{50}s at a variety of northern latitudes (30 – 50°N)

[c] Carryover to the next growing season is based on the percentage of applied oxathiapiprolin present in the soil column approximately 365 days after application.

[d] Maximum depth of parent test material infiltration into soil at concentrations > LOD (0.3 - 0.5 µg/kg). No transformation products were observed below 70 cm depth in any of the field studies.

Table 8 **Major transformation products of oxathiapiprolin observed in environmental fate studies.**

IN-RDT31 CAS Name: 1-[4-[4-[5-(2,6-Difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-4-hydroxy-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone CAS Number: 1151573-12-4 Formula: $C_{24}H_{22}F_5N_5O_3S$ Log K_{OW} = 2.95 **Observed in:** Soil (maximum 9.4% applied radiation)
IN-RAB06 CAS: 1-[2-[4-[4-[5-(2,6-Difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-oxoethyl]-3-(trifluoromethyl)-1H-pyrazole-5-carboxylic acid CAS Number: N/A Formula: $C_{24}H_{20}F_5N_5O_4S$ Log K_{OW} = -0.05 **Observed in:** Soil (maximum 13.5% applied radiation), water-sediment systems (< 10% applied radiation)
IN-E8S72 CAS: 5-(Trifluoromethyl)-1H-pyrazole-3-carboxylic acid CAS Number: 1297668-28-1 Formula: $C_5H_3F_3N_2O_2$ Log K_{OW} = -0.52 **Observed in:** Soil (maximum 11.7% applied radiation)
IN-P3X26 CAS: 2-[1-[2-[5-Methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]acetyl]-4-piperidinyl]-4-thiazolecarboxylic acid CAS Number: Not available Formula: $C_{16}H_{17}F_3N_4O_3S$ Log K_{OW}: 0.25 **Observed in:** Water (photolysis only; maximum 14.0% applied radiation)
IN-RYJ52 (combined isomers IN-RYJ52-I1 plus IN-RYJ52-I2) CAS: 1-[4-[4-[(1S,3S)-3-(2,6-Difluorophenyl)-1,3-dihydroxypropyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone CAS Number: Not available Formula: $C_{24}H_{25}F_5N_4O_3S$ IN-RYJ52-I1 Log K_{OW}: 2.13 IN-RYJ52-I2 Log K_{OW}: 2.24 **Observed in:** Water-sediment systems (maximum 32.7% applied radiation)

IN-S2R66
CAS: 1-[4-[4-[3-(2,6-Difluorophenyl)-1-hydroxypropyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone
CAS Number: Not available
Formula: $C_{24}H_{25}F_5N_4O_2S$

Log K_{OW}: 3.40
Observed in: Water-sediment systems (maximum 13.0% applied radiation)

IN-Q7D41
CAS: 1-[4-[4-[5-(2,6-Difluorophenyl)-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone
CAS Number: 1148046-55-0
Formula: $C_{24}H_{20}F_5N_5O_2S$

Log K_{OW}: 4.31
Observed in: Soil (<10% applied radiation), water-sediment systems (maximum 11.8% applied radiation)

IN-Q8F04
CAS: 1-[4-(4-Acetyl-2-thiazolyl)-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone
CAS Number: 1152179-05-1
Formula: $C_{17}H_{19}F_3N_4O_2S$

Log K_{OW}: 2.08
Observed in: Water-sediment systems (maximum 20.2% applied radiation)

IN-S2R67
CAS: 1-[4-[4-(1-Hydroxyethyl)-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone
CAS Number: N/A
Formula: $C_{17}H_{21}F_3N_4O_2S$

Log K_{OW}: 1.56
Observed in: Water-sediment systems (maximum 13.6% applied radiation)

IN-RDE10
CAS: 3-(2,6-Difluorophenyl)-3-hydroxy-1-[2-[1-[2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]acetyl]-4-piperidinyl]-4-thiazolyl]-1-propanone
CAS Number: N/A
Formula: $C_{24}H_{23}F_5N_4O_3S$

Log K_{OW}: 2.78
Observed in: Water-sediment systems (maximum 16.6% applied radiation)

2,6-DFBA / IN-YY147
CAS: 2,6-difluorobenzoic acid
CAS Number: 385-00-2

Formula: $C_7H_4F_2O_2$
Log K_{OW}: n/a [2,6-DFBA is a common transformation product of the registered technical grade active ingredient diflubenzuron (Reg. No. 25451); Public literature Log Kow values: -0.02 (Thus, 1988, as cited in FAO review for diflubenzuron), 1.18 to 1.92 (ChemSpider, 2015)]

Observed in: Water-sediment systems (maximum 18.2% applied radiation)

Table 9 **Comparison of the properties of oxathiapiprolin and its major soil transformation products with the leaching criteria of Cohen et al. (1984).**

Property	**Criteria of Cohen et al. (1984) indicating a potential for leaching**	**Meets criterion for leaching**			
		Parent	**IN-E8S72**	**IN-RAB06**	**IN-RDT31**
Solubility in water	>30 mg/L	No	Yes	Yes	No
K_d	<5 and usually <1 or 2	No	Yes	No	No
K_{oc}	<300	No	Yes	No	No
Henry's law constant	$<10^{-2}$ atm m^3/mol	Yes	NA	NA	NA
pK_a	Negatively charged (either fully or partially) at ambient pH	No	NA	NA	NA
Hydrolysis half-life	>20 weeks (>140 days)	Yes	NA	NA	NA
Soil photo-transformation half-life	>1 week (>7 days)	Yes	NA	NA	NA
Half-life in soil	>2 to 3 weeks (>14 to 21 days)	Yes	Yes	Yes for most soils tested	Yes

Table 10 **Estimated environmental concentrations (EECs) of oxathiapiprolin used for screening level risk assessment.**

Product	Application method	Maximum seasonal rate (g a.i./ha)	Terrestrial EEC		Aquatic EEC (mg a.i./L)	
			Soil exposure[1] (mg a.i./kg)	Foliar exposure[2] (g a.i./ha)	15 cm water[3]	80 cm water[3]
Oxathiapiprolin 100 g/L OD	**Soil drench and foliar application (field sprayer)**	2 × 280	0.246	452 (on vegetation) 554 (on soil)	0.369	0.0693

[1] Calculated based on a 7-day application interval, using the longest t_R in soil of 231 days and by assuming a soil bulk density of 1.5 g/cm^3 and a soil depth of 15 cm.

[2] Calculated using a foliar half-life of 10 days (on vegetation) or soil half-life of 231 days (on soil).

[3] Aquatic EECs are calculated by assuming oxathiapiprolin is applied direct overspray on water bodies of defferent depths and using the longest t_R of 229 days and a 7-day application interval.

[4] EECs for transformation products of oxathiapiprolin are presented in the appropriate risk assessment tables (Tables 16 and 23), along with the molecular weight ratios used to derive them from oxathiapiprolin EECs.

Table 11 **EECs in vegetation and insects after a direct over-spray as food sources for birds and small wild mammals.**

Environmental Compartment	fresh/dry weight ratios	Maximum residue concentration		Mean residue concentration	
		Concentration fresh weight (mg a.i./kg)	Concentration dry weight (mg a.i./kg)	Concentration fresh weight (mg a.i./kg)	Concentration dry weight (mg a.i./kg)
short range grass	3.3	96.8	319.5	34.4	113.5
leaves and leafy crops	11	54.7	602.1	18.1	199.0
long grass	4.4	44.3	195.1	14.5	63.7
forage crops	5.4	54.7	295.6	18.1	97.7
small insects	3.8	23.5	89.4	13.1	49.9
pods with seeds	3.9	5.9	22.9	2.8	10.9
large insects	3.8	5.9	22.3	2.8	10.7
grain and seeds	3.8	5.9	22.3	2.8	10.7
fruit	7.6	5.9	44.7	2.8	21.3

Note: EECs are based on the highest rate for foliar application to ginseng (i.e., 2 × 280 g a.i./ha) with a 7-day interval and a foliar half-life of 10 days.

Table 12 **Estimated daily exposure (EDE) levels on-field for birds and mammals.**

BIRDS			Maximum nomogram residues		Mean nomogram residues	
Generic bw (kg)	FIR (kg dw diet/d)	Food Guild (food item)	on-field		on-field	
			EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)	EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)
0.02	0.0051	Insectivore (small insects)	89.4	22.8	49.9	12.7
0.02	0.0051	Granivore (grain and seeds)	22.3	5.7	10.7	2.7
0.02	0.0051	Frugivore (fruit)	44.7	11.4	21.3	5.4
0.1	0.0199	Insectivore (small insects)	89.4	17.8	49.9	9.9
0.1	0.0199	Insectivore (large insects)	22.3	4.4	10.7	2.1
0.1	0.0199	Granivore (grain and seeds)	22.3	4.4	10.7	2.1
0.1	0.0199	Frugivore (fruit)	44.7	8.9	21.3	4.2
1	0.0581	Insectivore (small insects)	89.4	5.2	49.9	2.9
1	0.0581	Insectivore (large insects)	22.3	1.3	10.7	0.6
1	0.0581	Granivore (grain and seeds)	22.3	1.3	10.7	0.6
1	0.0581	Frugivore (fruit)	44.7	2.6	21.3	1.2
1	0.0581	Herbivore (short grass)	319.5	18.6	113.5	6.6
1	0.0581	Herbivore (long grass)	195.1	11.3	63.7	3.7
1	0.0581	Herbivore (forage crops)	295.6	17.2	97.7	5.7
1	0.0581	Herbivore (leafy foliage)	602.1	35.0	199.0	11.6

MAMMALS			Maximum nomogram residues		Mean nomogram residues	
			on-field		on-field	
Generic Body weight (kg)	FIR (kg dw diet/day)	Food Guild (food item)	EEC	EDE	EEC	EDE
			(mg a.i./kg diet)	(mg a.i./kg bw)	(mg a.i./kg diet)	(mg a.i./kg bw)
0.015	0.0022	Insectivore (small insects)	89.4	13.1	49.9	7.3
0.015	0.0022	Granivore (grain and seeds)	22.3	3.3	10.7	1.6
0.015	0.0022	Frugivore (fruit)	44.7	6.6	21.3	3.1
0.035	0.0045	Insectivore (small insects)	89.4	11.5	49.9	6.4
0.035	0.0045	Insectivore (large insects)	22.3	2.9	10.7	1.4
0.035	0.0045	Granivore (grain and seeds)	22.3	2.9	10.7	1.4
0.035	0.0045	Frugivore (fruit)	44.7	5.7	21.3	2.7
0.035	0.0045	Herbivore (short grass)	319.5	41.1	113.5	14.6
0.035	0.0045	Herbivore (long grass)	195.1	25.1	63.7	8.2
0.035	0.0045	Herbivore (forage crops)	295.6	38.0	97.7	12.6
0.035	0.0045	Herbivore (leafy foliage)	602.1	77.4	199.0	25.6
1	0.0687	Insectivore (small insects)	89.4	6.1	49.9	3.4
1	0.0687	Insectivore (large insects)	22.3	1.5	10.7	0.7
1	0.0687	Granivore (grain and seeds)	22.3	1.5	10.7	0.7
1	0.0687	Frugivore (fruit)	44.7	3.1	21.3	1.5

1	0.0687	Herbivore (short grass)	319.5	21.9	113.5	7.8
1	0.0687	Herbivore (long grass)	195.1	13.4	63.7	4.4
1	0.0687	Herbivore (forage crops)	295.6	20.3	97.7	6.7
1	0.0687	Herbivore (leafy foliage)	602.1	41.4	199.0	13.7

[a] Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used: Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g)$^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g)$^{0.651}$. For mammals, the "all birds" equation was used: FIR (g dry weight/day) = 0.235(BW in g)$^{0.822}$

[b] Large insects not considered to be a relevant food source for small birds and mammals.

[c] For granivorous species, only grains and seeds were considered as a relevant source of exposure (as opposed to seeds in pods, which were not considered).

[d] EDE = Estimated daily exposure is calculated using the following formula: (FIR/BW) × EEC. At the screening level, food items representing the most conservative EEC are used.

[e] Additional food items that could be considered to further characterize the risk.

Table 13 Effects of oxathiapiprolin technical, Oxathiapiprolin 100 g/L and 200 g/L SC formulations and the major transformation products on terrestrial organisms.

Test organisms	Test substance	Exposure	Endpoint (mg/kg dw soil)	Degree of toxicity/ comments	PMRA document number
Invertebrates					
Earthworm	Oxathiapiprolin	28-Day acute	LC_{50}: > 1000 mg a.i./kg dw soil	N/A / No mortality	2364630
		56-Day chronic	NOEC: 1000 mg a.i./kg dw soil	N/A	2364630
	Oxathiapiprolin 100 g/L OD	28-Day acute	LC_{50}: > 1000 mg/kg dw soil [> 100 mg a.i./kg dw soil]	N/A / No mortality	2365110
	Oxathiapiprolin 200 g/L SC	28-Day acute	LC_{50}: > 1000 mg/kg dw soil [>200 mg a.i./kg dw soil]	N/A / No mortality	2365238
	IN-E8S72	28-Day acute	LC_{50}: > 100 mg/kg dw soil	N/A / No mortality	2364628
		56-Day chronic	NOEC: 100 mg/kg dw soil	N/A	2364628
	IN-QPS10	28-Day acute	LC_{50}: > 100 mg/kg dw soil	N/A / No mortality	2364626
		56-Day chronic	NOEC: 100 mg/kg dw soil	N/A	2364626

	IN-RAB06	28-Day acute	LC$_{50}$: > 100 mg/kg dw soil	N/A / No mortality	2364622
		56-Day chronic	NOEC: 100 mg/kg dw soil	N/A	2364622
	IN-RDT31	28-Day acute	LC$_{50}$: > 100 mg/kg dw soil	N/A / No mortality	2364621
		56-Day chronic	NOEC: 100 mg/kg dw soil	N/A	2364621
Beneficial Arthropods					
Parasitoid wasp (*Aphidius rhopalosiphi*)	Oxathiapiprolin 100 g/L OD	48h-acute (glass surface)	LR$_{50}$: 1138.14 mL/ha [= 116 g a.i./ha] ER$_{50}$: > 700.29 mL /ha [> 71 g a.i./ha] (highest rate for survivors; no effect on reproduction at this level)	N/A	2364659
		48h-extended (plant surface)	LR$_{50}$: > 1960.78 mL /ha [> 200 g a.i./ha] ER$_{50}$: > 1960.78 mL /ha [> 200 g a.i./ha]	N/A	2364657
Predatory mite (*Typhlodromus pyri*)	Oxathiapiprolin 100 g/L OD	14d-residue contact (glass surface)	LR$_{50}$: > 1960.78 mL /ha [> 200 g a.i./ha] ER$_{50}$: > 1960.78 mL /ha [> 200 g a.i./ha]	N/A	2364658
		Field test (vineyards, Germany) 3 applications, 9 d spray interval at max rate: 588 mL Oxathiapiprolin 100 g/L OD/ha, equivalent to 60 g a.i./ha), at 400 L/ha spray volume.	No statistically significant reduction in predatory mite population ≥50% compared to the control. Max reduction compared to control was 20.4% at 6 DAA2 (31 days prior to study termination).	N/A	2364652
		Field test (vineyards, France) 3 applications, 9 & 8 d spray	No statistically significant reduction in predatory mite population ≥50%	N/A	2364654

		interval at max rate 588 mL Oxathiapiprolin 100 g/L OD /ha, equivalent to 60 g a.i./ha), at 100 L/ha spray volume.	compared to the control. Max reduction compared to control was 11.9% at 30 DAA3 (study termination).		
		Field test (vineyards, Italy) 3 applications, 10 d spray interval at max rate 588 mL Oxathiapiprolin 100 g/L OD/ha, equivalent to 60 g a.i./ha), at 800 L/ha spray volume.	No statistically significant reduction in predatory mite population ≥50% compared to the control. Max reduction compared to control was 13.1% at 7 DAA1 (42 days prior to study termination).	N/A	2364656
Green lacewing (*Chrysoperla carnea*)	Oxathiapiprolin 100 g/L OD	6-13d-extended (leaf surface)	LR$_{50}$: > 1960.78 mL /ha [> 200 g a.i./ha] ER$_{50}$: > 1960.78 mL /ha [> 200 g a.i./ha]	N/A	2364651
Predatory soil mite (*Hypoaspis aculeifer*)	Oxathiapiprolin	14d- extended (soil)	EC$_{50}$: >1000 mg a.i./kg soil d.w. NOEC: 1000 mg a.i./kg soil d.w.	N/A	2364650
	Oxathiapiprolin 100 g/L OD	14d- extended (soil)	EC$_{50}$: >1000 mg/kg soil d.w. [>100 mg a.i. /kg soil d.w.] NOEC: 1000 mg/kg soil d.w. [100 mg a.i. /kg soil d.w.]	N/A	2365112
	IN-E8S72	14d- extended (soil)	EC$_{50}$: >100 mg/kg soil d.w. NOEC: 100 mg/kg soil d.w.	N/A	2364648
	IN-QPS10	14d- extended (soil)	EC$_{50}$: >100 mg/kg soil d.w. NOEC$_{reproduction}$: 50 mg/kg soil d.w.	N/A	2364644

	IN-RAB06	14d- extended (soil)	EC_{50}: >100 mg/kg soil d.w. $NOEC_{reproduction}$: 25 mg/kg soil d.w.	N/A	2364639
	IN-RDT31	14d- extended (soil)	EC_{50}: >100 mg/kg soil d.w. NOEC: 100 mg/kg soil d.w.	N/A	2364634
Collembola (*Folsomia candida*)	Oxathiapiprolin	28d-extended (soil)	EC_{50}: >100 mg a.i./kg soil d.w. $NOEC_{reproduction}$: 25 mg a.i./kg soil d.w.	N/A	2364649
	Oxathiapiprolin 100 g/L OD	28d-extended (soil)	EC_{50}: >1000 mg/kg soil d.w. [>100 mg a.i./kg soil d.w.] $NOEC_{reproduction}$: 250 mg/kg soil d.w. [25 mg a.i./kg soil d.w.]	N/A	2365115
	IN-E8S72	28d-extended (soil)	EC_{50}: >100 mg/kg soil d.w. NOEC: 100 mg/kg soil d.w.	N/A	2364645
	IN-QPS10	28d-extended (soil)	EC_{50}: >100 mg/kg soil d.w. NOEC: 100 mg/kg soil d.w.	N/A	2364642
	IN-RAB06	28d-extended (soil)	EC_{50}: >100 mg/kg soil d.w. NOEC: 100 mg/kg soil d.w.	N/A	2364637
	IN-RDT31	28d-extended (soil)	EC_{50}: >100 mg/kg soil d.w. NOEC: 100 mg/kg soil d.w.	N/A	2364631
Bees					
Honeybee (*Apis mellifera*)	Oxathiapiprolin (TGAI)	48h-Oral	LD_{50}: >40.26 µg a.i./bee	Practically non-toxic	2364666
		48h-Contact	LD_{50}: >100 µg a.i./bee	Practically non-toxic	2364666
	Oxathiapiprolin 100 g/L OD	48h-Oral	LD_{50}: >137.44 µg a.i./bee	Practically non-toxic	2365109
		48h-Contact	LD_{50}: >100 µg a.i./bee	Practically non-toxic	2365109
		Semi-field brood/hive study	No significant effects on honey bee endpoints at 3	N/A	2364661

			× 60 or 3 × 120 g a.i./ha (3rd application carried out during full flowering and during daily bee flight). Observed effects included: a) at 3 × 180 g a.i./ha treatment: slight, but statistically higher elevation in mortality of pupae and young bees at high treatment level after 3rd application, b) at all treatment levels: slight reduction in flight activity after 3rd application (not considered biologically relevant), c) at all treatment levels: brood/compensation indices were slightly lower than controls and termination rates were higher than in controls (none were statistically significant).		
	Oxathiapiprolin 200 g/L SC	48h-Oral	LD_{50}: >231.9 µg a.i./bee	Practically non-toxic	2365236
		48h-Contact	LD_{50}: >200 µg a.i./bee	Practically non-toxic	2365236
	IN-E8S72	48h-Oral	LD_{50}: >109 µg/bee	Practically non-toxic	2364665
		48h-Contact	LD_{50}: >100 µg/bee	Practically non-toxic	2364665
	IN-WR791	48h-Oral	LD_{50}: >56.2 µg/bee	Practically non-toxic	2364663
		48h-Contact	LD_{50}: >100 µg/bee	Practically non-toxic	2364663

Birds					
Northern Bobwhite quail (*Colinus virginianus*)	Oxathiapiprolin	Acute oral	LD$_{50}$: >2250 mg a.i./kg bw	Practically non-toxic	2364766
		Acute Dietary (5-day)	LC$_{50}$:>5640 mg a.i./kg feed LD$_{50}$ >1280 mg a.i. /kg bw/d	Practically non-toxic	2364765
		Reproduction (21-week)	NOEC: 1230 mg a.i./kg feed NOEL: 106.7 mg a.i./kg bw/d	N/A	2364762
	Oxathiapiprolin 100g/L OD	Acute oral	LD$_{50}$: >2250 mg /kg bw [> 223.9 mg a.i. /kg bw]	Practically non-toxic	2365098
		Acute Dietary (5-day)	LC$_{50}$:>5640 mg/kg feed [> 561.2 mg a.i. /kg bw] LD$_{50}$ >1328 mg/kg bw/d [> 132.1 mg a.i./kg bw/d]	Practically non-toxic	2365100
Mallard duck (*Anas platyrhynchos*)	Oxathiapiprolin	Acute Dietary (5-day)	LC$_{50}$:>5640 mg a.i./kg feed LD$_{50}$ >2728 mg a.i. /kg bw/d	Practically non-toxic	2364764
		Reproduction (21-week)	NOEC: 920 mg a.i./kg feed NOEL: 117.4 mg a.i./kg bw/d	N/A	2364763
Zebra finch (*Poephila guttata*)		Acute oral	LD$_{50}$: >2250 mg a.i./kg bw	Practically non-toxic	2364767
Mammals					
Rat	Oxathiapiprolin	Acute oral	LD$_{50}$: >5000 mg a.i./kg bw	Practically non-toxic	2365151
		2-generation reproduction (dietary)	NOAEL: 411.4 mg a.i./kg bw/d	N/A	2365053 2454561
Vascular plants					
Vascular plant	Oxathiapiprolin 100 g/L OD	21-d Seedling emergence	ER$_{25}$: >584 g a.i./ha	N/A / No toxicity	2364756
		21-d Vegetative vigour	ER$_{25}$: >629 g a.i./ha	N/A / No toxicity	2364755

[1] USEPA classification (1985), where applicable.

Table 14 **Effects of oxathiapiprolin technical, Oxathiapiprolin 100 g/L formulation and the major transformation products on aquatic organisms.**

Test species	Test substance	Exposure	Endpoints	Degree of toxicity* / comments	PMRA document number
Freshwater algae					
Green algae (*Pseudokirchneriella subcapitata*)	Oxathiapiprolin	96h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >0.142 mg a.i./L	N/A / No significant effects	2366691
	Oxathiapiprolin 100g/L OD (EP)	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >0.54 mg a.i./L	N/A / Significant effects at < 50% inhibition	2365107
	IN-E8S72	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >101.5 mg/L	N/A / No significant effects	2366689
	IN-P3X26	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >66.6 mg/L	N/A / No significant effects	2366687
	IN-Q7D41	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >0.205 mg/L	N/A / No significant effects	2366685
	IN-Q8F061	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >7.53 mg/L	N/A / Significant effects at < 50% inhibition	2366682
	IN-QPS10	72h-Acute (static)	EyC$_{50}$ 0.814 mg/L	N/A	2366681
	IN-RAB06	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >96.9 mg/L	N/A / No significant effects	2366679
	IN-RDT31	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >11.4 mg/L	N/A / Significant effects at < 50% inhibition	2366677
	IN-RSE01	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >10.1 mg/L	N/A / Significant effects at < 50% inhibition	2366676
	IN-RYF52	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >15.3 mg/L	N/A / Significant effects at < 50% inhibition	2366675
	IN-S2K66	72h-Acute (static)	ErC$_{50}$ or EyC$_{50}$ >7.56 mg/L	N/A / Significant effects at < 50% inhibition	2366674

	IN-S2K67	72h-Acute (static)	E_rC_{50} or E_yC_{50} >83.5 mg/L	N/A / Significant effects at < 50% inhibition	2566675
Blue-green algae (*Anabaena flos-aquae*)	Oxathiapiprolin	96h-Acute (static)	E_rC_{50} or E_yC_{50} >0.193 mg a.i./L	N/A / No significant effects	2566696
Diatom (*Navicula pelliculosa*)	Oxathiapiprolin	96h-Acute (static)	E_rC_{50} or E_yC_{50} >0.163 mg a.i./L	N/A / No significant effects	2566698
Freshwater vascular plants					
Duckweed (*Lemna gibba*)	Oxathiapiprolin	7d-acute (static-semi-renewal)	E_rC_{50} or E_yC_{50} >0.700 mg a.i./L	N/A / No significant effects	2566667
Freshwater invertebrates					
Daphnia magna	Oxathiapiprolin	48h-Acute (static)	EC_{50}: 0.629 mg a.i./L	Highly toxic	2566712
		21d-Chronic (semi-static)	NOEC: 0.750 mg a.i./L	N/A / No significant effects	2566699
	DPX-QGU42 100g/L OD (EP)	48h-Acute (static)	EC_{50}: >0.822 mg a.i./L	No mortality up to achievable solubility limit[a]	2567104
	IN-E8S72	48h-Acute (static)	EC_{50}: >100 mg/L	Practically non-toxic	2566709
	IN-P3X26	48h-Acute (static)	EC_{50}: >67.7 mg/L	No mortality up to achievable solubility limit[a]	2566722
	IN-Q7D41	48h-Acute (static)	EC_{50}: >0.150 mg/L	No mortality up to achievable solubility limit[a]	2566721
	IN-QFD61	48h-Acute (static)	EC_{50}: 5.14 mg/L	Moderately toxic	2566720
	IN-QPS10	48h-Acute (static)	EC_{50}: 14.7 mg/L	Slightly toxic	2566719
	IN-RAB06	48h-Acute (static)	EC_{50}: >100 mg/L	Practically non-toxic	2566708
	IN-RDT31	48h-Acute (static)	EC_{50}: >10.5 mg/L	No mortality up to achievable solubility limit[a]	2566718
	IN-RSE11	48h-Acute (static)	EC_{50}: >10.2 mg/L	No mortality up to achievable solubility limit[a]	2566717

	IN-RYB52	48h-Acute (static)	EC_{50} >16.2 mg/L	No mortality up to achievable solubility limit[2]	2366716
	IN-S2K46	48h-Acute (static)	EC_{50} 0.805 mg/L	Highly toxic	2366719
	IN-S2K47	48h-Acute (static)	EC_{50} 56.2 mg/L	Slightly toxic	2366715
Midge (*Chironomus riparius*)	Oxathiapiprolin	48h-Acute (static)	EC_{50} >0.560 mg a.i./L	No mortality up to achievable solubility limit[2]	2366672
		28d-Chronic (static, spiked sediment)	% Emergence NOEC: 2.8 mg a.i./kg sed., or 0.17 mg a.i./L (overlying water)	N/A	2366670
		28d-Chronic (static, spiked water)	% Emergence NOEC = 0.099 mg a.i./L (overlying water)	N/A	2366669
	IN-Q7D41	28d-Chronic (static, spiked sediment)	Development rate NOEC: 35 mg a.i./kg sed., or 0.18 mg/L (overlying water)	N/A	2366668
Freshwater fish					
Rainbow Trout (*Oncorhynchus mykiss*)	Oxathiapiprolin	96h-acute (static)	LC_{50} >0.69 mg a.i./L	No mortality up to achievable solubility limit[2]	2366752
		ELS 90-day	NOEC: 0.460 mg a.i./L	N/A	2366756
	Oxathiapiprolin 100g/L OD (EP)	96h-acute (static)	LC_{50} >0.51 mg a.i./L	No mortality up to achievable solubility limit[2]	2367102
	IN-E8S72	96h-acute (static)	LC_{50} >100.6 mg/L	Practically non-toxic	2366758
	IN-P5X26	96h-acute (static)	LC_{50} >97.7 mg/L	Practically non-toxic	2366760
	IN-Q7D41	96h-acute (static)	LC_{50} >0.180 mg/L	No mortality up to achievable solubility limit[2]	2366748
	IN-QFD61	96h-acute (static)	LC_{50} >7.38 mg/L	No mortality up to achievable solubility limit[2]	2366747
	IN-QPS10	96h-acute (static)	LC_{50} 6.58 mg/L	Moderately toxic	2366746
	IN-RAB06	96h-acute (static)	LC_{50} >86.7 mg/L	No mortality up to achievable	2366754

				solubility limit²	
	IN-[illegible]	96h-acute (static)	LC50 >[illegible] mg/L	No mortality up to achievable solubility limit²	[illegible]
	IN-[illegible]	96h-acute (static)	LC50 >[illegible] mg/L	No mortality up to achievable solubility limit²	[illegible]
	IN-[illegible]	96h-acute (static)	LC50 >[illegible] mg/L	No mortality up to achievable solubility limit²	[illegible]
	IN-[illegible]	96h-acute (static)	LC50 >[illegible] mg/L	No mortality up to achievable solubility limit²	[illegible]
	IN-[illegible]	96h-acute (static)	LC50 =[illegible] mg/L	Practically non-toxic	[illegible]
Bluegill sunfish *(Lepomis macrochirus)*	Oxathiapiprolin	96h-acute (static)	LC50 >0.72 mg a.i./L	No mortality up to achievable solubility limit²	[illegible]
Marine organisms					
Saltwater diatom *(Skeletonema costatum)*	Oxathiapiprolin	96h-acute (static)	ErC50, EyC50 >[illegible] mg a.i./L	N/A / Significant effects at < 50% inhibition	[illegible]
Eastern oyster *(Crassostrea virginica)*	Oxathiapiprolin	96h-acute (static, limit test)	EC50 >[illegible] mg a.i./L	No significant effects up to achievable solubility limit²	[illegible]
Mysid shrimp *(Americamysis bahia)*	Oxathiapiprolin	96h-acute (static)	LC50 >[illegible] mg a.i./L	No significant mortality up to achievable solubility limit²	[illegible]
		28d life cycle (flow-through)	NOEC[illegible] [illegible] mg a.i./L	N/A	[illegible]
Sheepshead minnow *(Cyprinodon variegatus)*	Oxathiapiprolin	96h-acute (flow-through)	LC50 >[illegible] mg a.i./L	Not toxic up to functional solubility limit²	[illegible]
		ELS [illegible]-day	NOEC: [illegible] mg a.i./L	N/A	[illegible]

¹ USEPA classification, where applicable.
² Toxicity endpoint is higher than maximum achievable test concentration; therefore oxathiapiprolin considered not to be toxic up to its functional solubility limit within the test system.

Table 17 Risk to soil dwelling organisms as a result of direct in-field exposures

Organism	Exposure	Test Substance	Endpoint Value (mg a.i./kg soil d.w.)	EEC¹ (mg a.i./kg soil dw)	RQ	LOC Exceeded?

Earthworm (*Eisenia fetida*)	28-day Acute	Oxathiapiprolin	1/2 LC_{50} >500	0.246	<0.01	No
		Oxathiapiprolin 100g/L OD (EP)	1/2 LC_{50} >50	0.246	<0.01	No
		Oxathiapiprolin 200g/L SC (EP)	1/2 LC_{50} >100	0.246	<0.01	No
		IN-E8S72	1/2 LC50 >50	0.0825	<0.01	No
		IN-QPS10	1/2 LC50 >50	0.159	<0.01	No
		IN-RAB06	1/2 LC50 >50	0.260	<0.01	No
		IN-RDT31	1/2 LC50 >50	0.253	<0.01	No
	56-day Chronic (28-day exposure)	Oxathiapiprolin	NOEC = 1000	0.246	<0.01	No
		IN-E8S72	NOEC = 100	0.0825	<0.01	No
		IN-QPS10	NOEC = 100	0.159	<0.01	No
		IN-RAB06	NOEC = 100	0.260	<0.01	No
		IN-RDT31	NOEC = 100	0.253	<0.01	No
Springtail (*Folsomia candida*)	28-day Chronic	Oxathiapiprolin	NOEC = 25	0.246	0.01	No
		Oxathiapiprolin 100g/L OD (EP)	NOEC = 25	0.246	0.01	No
		IN-E8S72	NOEC = 100	0.0825	<0.01	No
		IN-QPS10	NOEC = 100	0.159	<0.01	No
		IN-RAB06	NOEC = 100	0.260	<0.01	No
		IN-RDT31	NOEC = 100	0.253	<0.01	No
Soil mites (*Hypoaspis aculeifer*)	14-day Reproduction	Oxathiapiprolin	NOEC = 1000	0.246	<0.01	No
		Oxathiapiprolin 100g/L OD (EP)	NOEC = 100	0.246	<0.01	No
		IN-E8S72	NOEC = 100	0.0825	<0.01	No
		IN-QPS10	NOEC = 50	0.159	<0.01	No
		IN-RAB06	NOEC = 25	0.260	0.01	No
		IN-RDT31	NOEC = 100	0.253	<0.01	No

[1] EECs for transformation products adjusted for molecular weight ratio relative to oxathiapiprolin: IN-E8S72 = (180.9/539.53), IN-QPS10 = (349.41/539.53), IN-RAB06 = (569.51/539.53), IN-RDT31 = (555.53/539.53).

Table 16 Screening level risk to foliar-dwelling organisms as a result of in-field and off-field exposure.

Application scenario		**EEC (g a.i./ha)**	**Screening Level RQ**[1]			**LOC exceeded?**
			Parasitoid wasp (*A. rhopalosiphi*) 48h-LR$_{50}$ = 116 g a.i./ha	**Predatory mite (*T. pyri*) 14d-LR$_{50}$ > 200 g a.i./ha**	**Green lacewing (*C. carnea*) 14d-LR$_{50}$ > 200 g a.i./ha**	
In-field	Direct foliar application: 2×280 g a.i./ha, 7-d interval	452	**3.96**	**<2.26**	**<2.26**	**Yes**
Off-field	Field spray (11%)	49.7	0.43	<0.25	<0.25	No

[1] Based on toxicity studies conducted on glass plates.

Table 17 Refinement of the risk to foliar-dwelling organisms from in-field and off-field exposure.

Application scenario		**EEC (g a.i./ha)**	**Tier I Refined RQ**[1]	**LOC exceeded?**
			Parasitoid wasp *A. rhopalosiphi* 48h-LR$_{50}$ > 200 g a.i./ha	
In-field	Direct foliar application: 2×280 g a.i./ha, 7-d interval	452	**<2.26**	**Yes**[2]
Off-field	Field spray (11%)	49.7	<0.25	No

[1] Based on 48 hour extended toxicity study conducted on leaf surfaces.

[2] Uncertainty in whether LOC of 1.0 was exceeded as endpoint based on no-effects up to highest tested dose.

Table 18 **Details of results from field studies on predatory mites with Oxathiapiprolin 100 g/L OD.**

Study type	Exposure and endpoints
Field test (vineyards, Germany) – predatory mite population monitored (PMRA # 2364652)	**Application rate: 3 × 60 g a.i./ha (9-day interval):** The maximum reduction of the predatory mite population (100.0% *Typhlodromus pyri*) when compared to the control was 20.4% at 6 DAA2 (31 days prior to study termination). LR_{50} > 180 g a.i./ha
Field test (vineyards, France) – predatory mite population monitored (PMRA # 2364654)	**Application rate: 3 × 60 g a.i./ha (9 and 8 -day intervals):** The maximum reduction of the predatory mite population (97.8% *Typhlodromus pyri* and 2.2% *Amblyseius* sp.) when compared to the control was 11.9% at 30 DAA3 (study termination). LR_{50} > 180 g a.i./ha
Field test (vineyards, Italy) – predatory mite population monitored (PMRA # 2364656)	**Application rate: 3 × 60 g a.i./ha (10-day interval):** The maximum reduction of the predatory mite population (100% *Kampimodromus aberrans* at last sampling) when compared to the control was 13.1% at 7 DAA1 (42 days prior to study termination). LR_{50} > 180 g a.i./ha

Table 19 **Screening Level EECs and RQ values for honeybees based on foliar and soil drench applications.**

Exposure route	EEC (µg ai/g)	Exposure to bee (µg ai/bee/day)	Endpoint (µg ai/bee)	RQ	LOC exceeded?
Foliar Spray Application at rate of 0.28 kg a.i./ha					
Adult acute contact	-	0.67	>100	<0.01	No
Adult oral acute	27.4	8.01	>40.26	<0.20	No
Soil Treatment at rate of 0.28 kg a.i./ha					
Adult oral acute	0.021	0.006	>40.26	<0.01	No

Table 20 Screening level risk to birds and mammals as a result of direct on-field soil and foliar exposure of oxathiapiprolin at a maximum seasonal application of 560 g a.i./ha.

	Toxicity (mg ai/kg bw/d)	Feeding Guild (food item)	EDE[a] (mg ai/kg bw)	RQ	LOC exceeded?
Small Bird (0.02 kg)					
Acute	225.00	Insectivore (small insects)	22.79	0.10	No
Reproduction	106.70	Insectivore (small insects)	22.79	0.21	No
Medium Sized Bird (0.1 kg)					
Acute	225.00	Insectivore (small insects)	17.79	0.08	No
Reproduction	106.70	Insectivore (small insects)	17.79	0.17	No
Large Sized Bird (1 kg)					
Acute	225.00	Herbivore (short grass)	18.56	0.08	No
Reproduction	106.70	Herbivore (short grass)	18.56	0.17	No
Small Mammal (0.015 kg)					
Acute	500.00	Insectivore (small insects)	13.11	0.03	No
Reproduction	411.40	Insectivore (small insects)	13.11	0.03	No
Medium Sized Mammal (0.035 kg)					
Acute	500.00	Herbivore (short grass)	41.08	0.08	No
	500.00	Herbivore (leafy foliage)	77.41	0.15	No
Reproduction	411.40	Herbivore (short grass)	41.08	0.10	No
	411.40	Herbivore (leafy foliage)	77.41	0.19	No
Large Sized Mammal (1 kg)					
Acute	500.00	Herbivore (short grass)	21.95	0.04	No
	500.00	Herbivore (leafy foliage)	41.37	0.08	No
Reproduction	411.40	Herbivore (short grass)	21.95	0.05	No
	411.40	Herbivore (leafy foliage)	41.37	0.10	No

[a] EDE = Estimated daily exposure; is calculated using the following formula: (FIR/BW) × EEC. Where FIR is Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:

Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = $0.398(\text{BW in g})^{0.850}$

All birds Equation (body weight > 200 g): FIR (g dry weight/day) = $0.648(\text{BW in g})^{0.651}$.

For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = $0.235(\text{BW in g})^{0.822}$

At the screening level, food items representing the most conservative EEC for each size guild are used.

Table 21 Screening level risk assessment of Oxathiapiprolin 100 g/L OD to non-target terrestrial vascular plants at a maximum seasonal application of 560 g a.i./ha.

Exposure	Endpoint ER_{25} (g a.i./ha)	EEC g a.i./ha	RQ	LOC exceeded?
Seedling emergence	>584	554	< 0.95	No
Vegetative vigour	>629	452	< 0.72	No

Table 22 Screening level risk to aquatic organisms.

Organism	Exposure	Test Substance	Endpoint Value (mg a.i./L)	EEC^{f} (mg a.i./L)	RQ	LOC Exceeded?
Freshwater Species						
Algae						
Green algae: (*Pseudokirchneriella subcapitata)*	Acute 96-hour static	Oxathiapiprolin	1/2 ErC$_{50}$ or EyC$_{50}$ >0.071	0.0693	<0.98	No
	Acute 72-hour static	Oxathiapiprolin 100g/L (EP)	1/2 ErC$_{50}$ or EyC$_{50}$ >0.27	0.0693	<0.26	No
		IN-E8S72	1/2 ErC$_{50}$ or EyC$_{50}$ >51	0.0232	<0.01	No
		IN-P3X26	1/2 ErC$_{50}$ or EyC$_{50}$ >33.3	0.0517	<0.01	No
		IN-Q7D41	1/2 ErC$_{50}$ or EyC$_{50}$ >0.103	0.0690	<0.67	No
		IN-QFD61	1/2 ErC$_{50}$ or EyC$_{50}$ >3.77	0.0514	<0.01	No
		IN-QPS10	1/2 EyC$_{50}$ = 0.407	0.0449	0.11	No
		IN-RAB06	1/2 ErC$_{50}$ or EyC$_{50}$ >48	0.0731	<0.01	No
		IN-RDT31	1/2 ErC$_{50}$ or EyC$_{50}$ >5.7	0.0714	<0.01	No
		IN-RSE01	1/2 ErC$_{50}$ or EyC$_{50}$ >5.1	0.0697	<0.01	No
		IN-RYJ52	1/2 ErC$_{50}$ or EyC$_{50}$ >7.65	0.0699	<0.01	No
		IN-S2K66	1/2 ErC$_{50}$ or EyC$_{50}$ >3.78	0.0679	<0.02	No
		IN-S2K67	1/2 ErC$_{50}$ or EyC$_{50}$ >41.8	0.0517	<0.01	No
Blue-green algae *(Anabaena flos-aquae)*	Acute 96-hour static	Oxathiapiprolin	1/2 ErC$_{50}$ or EyC$_{50}$ >0.097	0.0693	<0.71	No
Diatom *(Navicula pelliculosa)*	Acute 72-hour static	Oxathiapiprolin	1/2 ErC$_{50}$ or EyC$_{50}$ >0.082	0.0693	<0.85	No

Plants						
Duckweed *(Lemna gibba)*	Acute 7-day semi-static	Oxathiapiprolin	1/2 ErC_{50} of EyC_{50} >0.395	0.0693	<0.18	No
Invertebrates						
Daphnia magna	Acute 48-hour static	Oxathiapiprolin	1/2 EC_{50} = 0.315	0.0693	0.22	No
	Chronic 21-days semi-static	Oxathiapiprolin	NOEC = 0.750	0.0693	0.09	No
	Acute 48-hour static	Oxathiapiprolin 100g/L (EP)	1/2 EC_{50} > 0.411	0.0693	<0.17	No
		IN-E8S72	1/2 EC_{50} >50	0.0232	<0.01	No
		IN-P3X26	1/2 EC_{50} >33.9	0.0517	<0.01	No
		IN-Q7D41	1/2 EC_{50} >0.075	0.0690	<0.92	No
		IN-QFD61	1/2 EC_{50} = 2.57	0.0514	0.02	No
		IN-QPS10	1/2 EC_{50} = 7.35	0.0449	0.01	No
		IN-RAB06	1/2 EC_{50} >47.7	0.0731	<0.01	No
		IN-RDT31	1/2 EC_{50} >5.3	0.0714	<0.01	No
		IN-RSE01	1/2 EC_{50} >5.1	0.0697	<0.01	No
		IN-RYJ52	1/2 EC_{50} >8.1	0.0699	<0.01	No
		IN-S2K66	1/2 EC_{50} = 0.208	0.0679	0.33	No
		IN-S2K67	1/2 EC_{50} >29.6	0.0517	<0.01	No
Midge *(Chironomus riparius)*	Acute 48-hour static	Oxathiapiprolin	1/2 EC_{50} >0.28	0.0693	<0.25	No
	Chronic 28-days static, spiked sediment	Oxathiapiprolin	NOEC = 0.17	0.0693	0.41	No
	Chronic 28-days static, spiked water	Oxathiapiprolin	NOEC = 0.099	0.0693	0.70	No
	Chronic 28-days static, spiked sediment	IN-Q7D41	NOEC = 0.14	0.0690	0.49	No

Fish						
Rainbow trout *(Oncorhynchus mykiss)*	Acute 96-hour flow-through	Oxathiapiprolin	1/10 LC_{50} >0.069	0.0693	<1.00	No
	ELS 90-day	Oxathiapiprolin	NOEC = 0.460	0.0693	0.15	No
	Acute 96-hour static	Oxathiapiprolin 100g/L (EP)	1/10 LC_{50} >0.051	0.00693	<1.36	No[a]
		IN-E8S72	1/10 LC_{50} >10.2	0.0232	<0.01	No
		IN-P3X26	1/10 LC_{50} >6.8	0.0517	<0.01	No
		IN-Q7D41	1/10 LC_{50} >0.018	0.0690	<3.83	No[b]
		IN-QFD61	1/10 LC_{50} >0.738	0.0514	<0.07	No
		IN-QPS10	1/10 LC_{50} = 0.654	0.0449	0.07	No
		IN-RAB06	1/10 LC_{50} >5.0	0.0731	<0.01	No
		IN-RDT31	1/10 LC_{50} >1.16	0.0714	<0.06	No
		IN-RSE01	1/10 LC_{50} >0.984	0.0697	<0.07	No
		IN-RYJ52	1/10 LC_{50} >1.38	0.0699	<0.05	No
		IN-S2K66	1/10 LC_{50} >0.748	0.0679	<0.09	No
		IN-S2K67	1/10 LC_{50} >8.25	0.0517	<0.01	No
Bluegill sunfish *(Lepomis macrochirus)*	Acute 96-hour flow-through	Oxathiapiprolin	1/10 LC_{50} >0.072	0.0693	<0.96	No
Amphibians	Acute (96 hours)	Oxathiapiprolin	1/10 LC_{50} >0.069	0.369	**<5.35**	**Yes**[c]
	Chronic (Early Life Stage (90 days)	Oxathiapiprolin	NOEC = 0.460	0.369	0.80	No
Marine Species						
Algae						
Saltwater diatom *(Skeletonema costatum)*	Acute 96-hour static	Oxathiapiprolin	1/2 ErC_{50} or EyC_{50} >0.230	0.0693	<0.30	No
Invertebrates						
Mollusk Eastern oyster *(Crassostrea virginica)*	Acute 96-hour flow-through	Oxathiapiprolin	1/2 EC_{50} >0.165	0.0693	<0.42	No
Crustacean mysid *(Americamysis bahia)*	Acute 96-hour flow-through	Oxathiapiprolin	1/2 LC_{50} >0.32	0.0693	<0.22	No

	Chronic 32-day flow through	Oxathiapiprolin	NOEC = 0.058	0.0693	1.19	No[d]
Fish						
Sheepshead minnow (*Cyprinodon variegates*)	Acute 96-hour flow-through	Oxathiapiprolin	1/10 LC_{50} >0.065	0.0693	<1.07	No[e]
	ELS 90-day	Oxathiapiprolin	NOEC = 0.230	0.0693	0.30	No

[a] Risk is not expected for exposure to the end use product as no mortality was seen up to highest achievable test concentration with the technical grade active ingredient.

[b] Risk is not expected for exposure to this transformation product, as the EEC, corrected for observed amount of IN-Q7D41 in the water column of the aerobic water biotransformation study (≤1.5% of applied oxathiapiprolin), results in a RQ <0.1.

[c] There is uncertainty in the potential for risk as there were no effects up to the highest achievable solubility of the chemical in the test system (i.e., the LC_{50} was 3.7x greater than the limit of solubility for oxathiapiprolin in distilled water).

[d] Risk is not expected for chronic exposure to marine invertebrates given the marginal exceedence of the LOC of 1.0 and the conservative assumptions for marine exposure.

[e] Risk is not expected for acute exposure to marine fish due to the marginal exceedence of the LOC and as no mortality was observed in the study up to the highest achievable test concentration for the technical grade active ingredient.

[f] EECs for transformation products adjusted for molecular weight ratio relative to oxathiapiprolin: IN-E8S72 = (180.9/539.53), IN-QPS10 = (349.41/539.53), IN-RAB06 = (569.51/539.53), IN-RDT31 = (555.53/539.53), IN-P3X26 = (402.4/539.53), IN-Q7D41 = (537.13/539.53), IN-QFD61 = (400.4/539.53), IN-RSE01 = (542.53/539.53), IN-RYJ52 = (544.55/539.53), IN-S2K66 = (528.55/539.53), IN-S2K67 = (402.44/539.53).

Table 23 Risk assessment of Oxathiapiprolin 100 g/L OD Fungicide at 140 g a.i./ha to amphibians in a 15-cm deep water body.

Organism	Exposure	Endpoint (mg a.i./L)	EEC (mg a.i./L)	RQ
15-cm deep water body				
Amphibians	Acute	>0.069	0.091	<1.3

Table 24 Refined risk assessment of Oxathiapiprolin 100 g/L OD Fungicide to amphibians via spray drift to a 15-cm deep water body.

Organism	Exposure	Endpoint (mg a.i./L)	Max seasonal rate (g a.i./ha)	Off-field	
				11% drift (ground spray, fine droplets)	
				EEC (mg a.i./L)	RQ
15-cm deep water body					
Amphibians	Acute	>0.069	140 g a.i./ha	0.010	<0.15
			560 g a.i./ha	0.041	<0.59

Table 25 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria							
TSMP Track 1 Criteria	**TSMP Track 1 Criterion value**		**Active Ingredient**	**Major soil transformation products**			
				IN-RAB06	**IN-RDT31**	**IN-E8S72**	**IN-QPS10[5]**
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes	Yes	Yes	Yes	Yes
Predominantly anthropogenic[2]	Yes		Yes	Yes	Yes	Yes	Yes
Persistence[3]:	Soil	Half-life $\geq$ 182 days	Yes[6] DT_{50}: 16 – 134 days $t_{1/2}$rep: 231 days (longest of six values)	Yes DT_{50}: 3 – 201 days $t_{1/2}$rep: 215 (longest of ten values)	Yes DT_{50}: 50 – > 1000 days $t_{1/2}$rep: >1000 (longest of five values)	Yes DT_{50}: 271 – 685 days $t_{1/2}$rep: >1000 (longest of five values)	Yes DT_{50}: 4 – 364 days $t_{1/2}$rep: 364 (longest of four values)
	Water/Sediment Whole System	Half-life $\geq$ 182 days (water) $\geq$ 365 days (sediment)	No[7] DT_{50}: 24 – 45 days $t_{1/2}$rep: 229 (longest of two $t_{1/2}$rep values)	NA	NA	NA	NA
	Air	Half-life $\geq$ 2 days or evidence of long range transport	NA (non-volatile)	NA	NA	NA	NA
Bioaccumulation[4]	Log $K_{OW} \geq 5$		No 3.6 (at pH 7)	No -0.05	No 2.95	No -0.52	No -2.02
	BCF $\geq$ 5000		No $\leq$ 87 whole fish (kinetic and steady state BCF)	NA	NA	NA	NA
	BAF $\geq$ 5000		NA	NA	NA	NA	NA
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4] Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{OW}).
[5] IN-QPS10 was considered to be a major soil transformation product by the applicant, but not by the PMRA.
[6] Oxathiapiprolin meets the TSMP persistence criteria for soil based on the longest available representative half-life of 231 days.
[7] Oxathiapiprolin meets the TSMP persistence criteria for water based on a whole-system representative half-life of 229 days; however, oxathiapiprolin is not expected to be persistent in water (DT_{50} 6 – 14 days) as it will readily partition to sediments. In sediments, representative half-lives of up to 249 days are below the criteria of ≥ 365 days. Aquatic transformation products: Persistence data are not available for oxathiapiprolin aquatic transformation products; however, it is not expected to form any major aquatic transformation products that meet all Track 1 criteria based on Log K_{ow} values: IN-RYJ52 (Log K_{ow} = 2.24), IN-S2K66 (Log K_{ow} = 3.41), IN-Q7D41(Log K_{ow} = 4.31), IN-RSE01 (Log K_{ow} = 2.78), IN-S2K67 (Log K_{ow} = 1.56), IN-QFD61 (Log K_{ow} = 2.05), 2,6-DFBA (Log K_{ow} ≤ 1.92) and IN-P3X26 (Log K_{ow} = 0.25). In aerobic water-sediment systems, oxathiapiprolin transforms directly to IN-Q7D41, and levels of this transformation product generally increased until study conclusion. The Log K_{ow} for IN-Q7D41 is greater than that of the parent oxathiapiprolin, however it is structurally identical to the parent, except for having two fewer hydrogen atoms and is therefore not expected to be any more bioaccumulative than oxathiapiprolin.

Table 26 Registered Alternatives (as of May, 2015)

The following fungicides are registered for control or suppression of the subject diseases. The fungicide classes indicated in this table may not be registered on all crops within a crop group. Seed treatment fungicides are not included in the table.

Crop(s) / Crop Group	Disease	Mode of Action Groups*
Brassica Vegetables	Downy mildew	7, 11, 21, 33, 40, 43, 44, 7+11, 7+40, M
Bulb Vegetables	Downy mildew	7, 11, 33, 40, 44, M, 4+M, 7+11
Cucurbit Vegetables	Downy mildew	11, 21, 28, 33, 40, 43, 44, 45, M, NC, 28+M, 40+45, U+M
	Phytophthora blight	33, 40, 43, 44, 40+45
Leafy Vegetables	Downy mildew	4, 11, 21, 33, 40, 43, 44, 45, M, U, 4+M, 7+11, 40+45
Tomato, pepper, eggplant	Late blight	11, 21, 28, 33, 40, 43, 44, M, NC, 11+27, 28+M, 40+45
	Phytophthora blight	29, 40, 43, 44, 45, 3+11, 40+45
Potato	Late blight	11, 21, 22, 27, 29, 33, 40, 43, 45, M, U, 4+M, 11+27
Tobacco	Blue mould	4, 11, 33, M, P, 40+M
Ginseng	*Phytophthora* blight and/or root rot	4, 11, 33, 40, 44, M
Succulent pea	Downy mildew	11, 7+11

*M=multi-site, NC=Not classified, P=host plant defence induction, U=unknown

Table 27 List of Supported Uses

Table 27.1 Dupont Zorvec Enicade Fungicide / Orondis Fungicide

Crop / Crop Group	Disease claim	Use Pattern
Head and Stem Brassica Vegetables (Crop Group 5A) Broccoli; Broccoli, Chinese (gai lon); Brussels sprouts; Cabbage; Cabbage, Chinese (napa); Cabbage, Chinese, mustard (gai choy); Cauliflower; Cavolo broccoli; Kohlrabi	Control of downy mildew (*Peronospora parasitica*)	**Rates:** 0.175 to 0.35 L/ha (17.5 – 35 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 5 – 10 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
Bulb Vegetables (Crop Group 3) Chive, fresh leaves; chive, Chinese, fresh leaves; garlic, bulb; garlic, great-headed, bulb; garlic, serpent, bulb; kurrat; lady's leek; leek; leek, wild; onion, Beltsville bunching; onion, bulb;onion, Chinese, bulb; onion, fresh onion, green; onion, macrostem; onion, pearl; onion, potato, bulb; onion, tree, tops; onion, Welsh, tops; shallot, bulb; shallot, fresh leaves; cultivars, varieties, and/or hybrids of these.	Control of downy mildew (*Peronospora destructor*)	**Rates:** 0.0875 – 0.35 L/ha (8.75 – 35 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 5 – 10 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
Cucurbit Vegetables (Crop Group 9) Chinese waxgourd (Chinese preserving melon); citron melon; cucumber (field + greenhouse foliar only); gherkin; gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra); Momordica spp. (includes balsam apple, balsam pear,	Control of downy mildew (*Pseudoperonospora cubensis*)	**Rates:** 0.0875 to 0.35 L/ha (8.75 – 35 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 5 – 14 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
	Control of phytophthora blight (*Phytophthora capsici*)	**Foliar Rates:** 0.175 to 0.35 L/ha (17.5 – 35 g a.i./ha).

bittermelon, Chinese cucumber), muskmelon (includes cantaloupe); pumpkin; squash, summer; squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash), watermelon *Greenhouse cucumber*		**Drench rates:** 0.7 to 2.8L/ha (70 – 280 g a.i./ha) **Timing:** Begin applications prior to disease development. Continue foliar applications on a 5 – 14 day interval and soil applications on a 7 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
Leafy Vegetables (Crop Group 4) Amaranth, leafy; Arugula, Cardoon, Celery, Celery (Chinese), Celtuce, Chevril, Chrysanthemum (edible leaved), Chrysanthemum (garland), Corn Salad, Cress (garland), Cress (upland), Dandelion leaves, Dock, Endive, Florence Fennel, Lettuce (head & leaf), Orach, Parsley leaves, Purslane (garden), Purslane (winter), Radicchio, Rhubarb, Spinach, Spinach (vine), Spinach (New Zealand), Swiss Chard	Control of downy mildew (*Bremia lactucae, Peronospora* spp.)	**Rates:** 0.175 to 0.35 L/ha (17.5 – 35 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 5 – 14 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
Tomato, Pepper, Eggplant Greenhouse tomato Greenhouse pepper	Control of late blight (*Phytophthora infestans*)	**Rates:** 0.175 to 0.35 L/ha (17.5 – 35 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 5 – 14 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
	Control of phytophthora blight (*Phytophthora capsici*)	**Foliar Rates:** 0.175 to 0.35 L/ha (17.5 – 35 g a.i./ha) **Drench rates:** 0.7 to 2.8L/ha (70 – 280

		g a.i./ha) **Timing:** Begin applications prior to disease development. Continue foliar applications on a 7 – 10 day interval and soil applications on a 7 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
Potato	Control of late blight (*Phytophthora infestans*)	**Rates:** 0.12 to 0.55 L/ha (12 – 55 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 7 – 14 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
Tobacco	Control of blue mould (*Peronospora tabacina*)	**Rates:** 0.20 – 0.55 L/ha (20 – 55 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 7 – 14 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
Ginseng	Control of phytophthora foliar blight and root rot (*Phytophthora cactorum*)	**Rates:** 0.7 – 2.8 L/ha (70 – 280 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 7 – 14 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.
Succulent pea (*Pisum* spp., includes dwarf pea, edible-pod pea, snow pea, sugar snap pea, English pea, garden pea, green pea)	Control of downy mildew (*Peronospora viciae*)	**Rates:** 0.175 to 0.55 L/ha (17.5 – 55 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 7 – 14 day interval. **Other:** Use higher rate and shorter interval when disease pressure is high.

Resistance Management: Do not follow soil applications of Dupont *Zorvec* Enicade Fungicide, Orondis Fungicide, Dupont *Zorvec* Epicaltra Fungicide, or OXTP 200SC Fungicide with foliar applications of Dupont *Zorvec* Enicade Fungicide or Orondis Fungicide. Use either soil applications or foliar applications but not both for the control of relevant disease.

Do not make more than 4 applications of product per crop by either method. Where multiple crop cycles are produced in the same year, do not exceed 6 foliar applications per hectare per year for the same crop.

Do not use for more than 1/3 of the total foliar fungicide applications. Maximum seasonal use rate is 1.4 L/ha for foliar use, except for ginseng which is 5.6 L/ha.

Do not use for more than 1/3 of the total soil fungicide applications. Maximum seasonal soil use rate is 5.6 L/ha.

Table 27.2 Dupont *Zorvec* Epicaltra Fungicide / OXTP 200SC Fungicide

Crop / Crop Group	Disease claim	Use Pattern
Cucurbit Vegetables (Crop Group 9) Chinese waxgourd (Chinese preserving melon), citron melon, cucumber, gherkin, gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra), Momordica spp (includes balsam apple, balsam pear, bittermelon, Chinese cucumber), muskmelon (includes cantaloupe), pumpkin, squash, summer, squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash), watermelon	Control of phytophthora blight (*Phytophthora capsici*)	**Rates:** 0.35 to 1.40 L/ha (70 – 280 g a.i./ha) **Timing:** Begin applications prior to disease development and continue on a 7 day interval. **Other:** Apply at plant, in furrow, drip or in transplant water. Use higher rate when disease pressure is high.

<table>
<tr><td>Tomato, Pepper, Eggplant</td><td>Control of phytophthora blight (<i>Phytophthora capsici</i>)</td><td>Rates: 0.35 to 1.4L/ha (70 – 280 g a.i./ha)
Timing: Begin applications prior to disease development and continue on a 7 day interval.
Other: Apply at plant, in furrow, drip or in transplant water. Use higher rate when disease pressure is high.</td></tr>
<tr><td colspan="3">Resistance Management: Do not make more than 4 applications of product per crop. The maximum seasonal use rate 2.8 L/ha.
Do not follow soil applications of Dupont Zorvec Epicaltrin Fungicide and OXTP 200SC Fungicide with foliar applications of Dupont Zorvec Enicade Fungicide and Orondis Fungicide. Use either soil applications or foliar applications but not both to control the relevant disease.</td></tr>
</table>

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Oxathiapiprolin is a new active ingredient which is concurrently being registered in Canada and the United States. The MRLs proposed for oxathiapiprolin in Canada are the same as corresponding tolerances to be promulgated in the United States, except for imported grapes and livestock commodities, in accordance with Table 1.

Once established, the American tolerances for oxathiapiprolin will be listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs[9] listed for oxathiapiprolin in or on any commodity on the Codex Alimentarius Pesticide Residues in Food website.

Table 1 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Grapes	Not Established	0.7	Not Established
Eggs, milk, fat, meat and meat byproducts of cattle, goats, horses, hogs and sheep	0.01	Not Established	Not Established

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada

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[9] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2365231	2013, Description and validation of the analytical methods for determination of impurities in technical grade DPX-QGU42, DACO: 2.13.4, Document K,IIA 4.2.3 CBI
2365234	2013, Validation of the analytical method for determination of DPX-QGU42 in technical grade products, DACO: 2.13.1, Document K,IIA 4.2.1 CBI
2365237	2013, Determination of DPX-QGU42 in technical grade DPX-QGU42, DACO: 2.13.1, Document K,IIA 4.2.1
2365246	2011, DPX-QGU42: Laboratory study of dissociation constants in water, DACO: 2.14.10,8.2.3.2, Document K,IIA 2.9.5
2365255	2011, DPX-QGU42: Laboratory study of n-octanol / water partition coefficient, DACO: 2.14.11, Document K,IIA 2.8.1,IIA 2.8.2
2365261	2012, DPX-QGU42: Solubility in organic solvents, DACO: 2.14.8, Document K,IIA 2.7
2365264	2013, DPX-QGU42: Solubility in organic solvents, DACO: 2.14.8, Document K,IIA 2.7
2365267	2013, DPX-QGU42: Laboratory study of water solubility, DACO: 2.14.7, Document K,IIA 2.6
2365270	2012, DPX-QGU42: Laboratory study of recording UV-VIS absorption spectra, IR, NMR and mass spectra, DACO: 2.13.2,2.14.12, Document K,IIA 2.5.1.1,IIA 2.5.1.2,IIA 2.5.1.3,IIA 2.5.1.4,IIA 2.5.1.5
2365272	2013, Henry's law constant for DPX-QGU42, DACO: 2.16, Document K,IIA 2.3.2
2365274	2012, DPX-QGU42: Laboratory study of vapour pressure, DACO: 2.14.9, Document K,IIA 2.3.1
2365277	2011, DPX-QGU42: Laboratory study of bulk density, DACO: 2.14.6, Document K,IIA 2.2
2365279	2012, DPX-QGU42 metabolites: Laboratory study of adsorption coefficient (Koc) and partition coefficient (Kow) by HPLC method, DACO: 2.16,8.2.4.2, Document K,IIA 2.18,IIA 7.4.2
2365284	2013, IN-RDT31: Laboratory study of water solubility, DACO: 2.16, Document K,IIA 2.18
2365286	2013, IN-RAB06: Laboratory study of water solubility, DACO: 2.16, Document K,IIA 2.18
2365288	2013, IN-QPS10: Laboratory study of water solubility, DACO: 2.16, Document K,IIA 2.18
2365290	2013, IN-E8S72: Laboratory study of water solubility, DACO: 2.16, Document K,IIA 2.18

2365292	2011, DPX-QGU42: Stability to normal and elevated temperatures, metal and metal ions, DACO: 2.14.13, Document K,IIA 2.17.2
2365295	2013, DPX-QGU42: Laboratory study of storage stability and corrosion characteristics, DACO: 2.14.14, Document K,IIA 2.17.1
2365296	2011, DPX-QGU42 : Laboratory study of physicochemical properties for color, odor, physical state, relative density and pH, DACO: 2.14.1,2.14.2,2.14.3,2.14.6,2.16, Document K,IIA 2.16,IIA 2.2,IIA 2.4.1,IIA 2.4.2
2365297	2011, DPX-QGU42 (PAI): Laboratory study of physicochemical properties for color, odor, physical state, relative density and pH, DACO: 2.14.1,2.14.2,2.14.3,2.14.6,2.16, Document K,IIA 2.16,IIA 2.2,IIA 2.4.1,IIA 2.4.2
2365298	2011, DPX-QGU42: Laboratory study of surface tension, DACO: 2.16, Document K,IIA 2.14
2365303	2012, DPX-QGU42 (technical): Laboratory study of flammability, autoflammability, oxidizing and explosive properties, DACO: 2.16, Document K,IIA 2.11.1,IIA 2.11.2,IIA 2.13,IIA 2.15
2365305	2011, DPX-QGU42 (technical): Laboratory study of melting point, boiling point and decomposition point, DACO: 2.14.13,2.14.4,2.14.5, Document K,IIA 2.1.1,IIA 2.1.2,IIA 2.1.3
2365307	2011, DPX-QGU42 (PAI): Laboratory study of melting point, boiling point and decomposition point, DACO: 2.14.13,2.14.4,2.14.5, Document K,IIA 2.1.1,IIA 2.1.2,IIA 2.1.3
2365310	2013, Oxathiapiprolin (DPX-QGU42): Identity, composition, and certified limits, DACO: 2.12.1,2.12.2, Document K,IIA 1.9.2 CBI
2365317	2013, Technical grade oxathiapiprolin (DPX-QGU42): Manufacturing description and formation of impurities, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.2,2.13.4, Document K,IIA 1.10.2,IIA 1.8.1,IIA 1.8.2 CBI
2365319	2013, Characterization of [CBI REMOVED], DACO: 2.13.3, Document K,IIA 1.11.2 CBI
2365322	2013, Characterization of [CBI REMOVED], DACO: 2.13.3, Document K,IIA 1.11.2 CBI
2365324	2013, Characterization of [CBI REMOVED], DACO: 2.13.3, Document K,IIA 1.11.2 CBI
2365327	2013, Characterization of [CBI REMOVED], DACO: 2.13.3, Document K,IIA 1.11.2 CBI
2365331	2013, Batch analysis of DPX-QGU42 technical, DACO: 2.13.3, Document K,IIA 1.11.1 CBI
2365335	2013, Batch analysis of DPX-QGU42 technical, DACO: 2.13.3, Document K,IIA 1.11.1 CBI
2365338	2013, Batch analysis of DPX-QGU42 technical, DACO: 2.13.3, Document K,IIA 1.11.1 CBI
2365340	2013, Batch analysis of DPX-QGU42 technical, DACO: 2.13.3, Document K,IIA 1.11.1 CBI
2436678	2012, RE-Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436679	2012, Determination of organic impurities by [CBI REMOVED]Primary and secondary data GLP Study No.: 110/12/61, DACO: 2.11.4,2.12 CBI

2436680	2013, RE-Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436681	2013, Determination of organic impurities by [CBI REMOVED]Primary and secondary data GLP Study No.: 434/13/61, DACO: 2.11.4,2.12 CBI
2436682	2010, 1H NMR Spectrum of [CBI REMOVED] DACO: 2.11.4,2.12 CBI
2436683	2014, [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436684	2011, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436685	2011, Determination of organic impurities by [CBI REMOVED]Primary and secondary data GLP Study No.: 103/11/61, DACO: 2.11.4,2.12 CBI
2436686	2013, [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436687	2012, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436688	2012, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 44/12/61, DACO: 2.11.4,2.12 CBI
2436689	2013, RE-Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436690	2013, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 85/13/61, DACO: 2.11.4,2.12 CBI
2436691	2009, Sample #12, IN Code [CBI REMOVED], Notebook: D100090 Page: 56, DACO: 2.11.4,2.12 CBI
2436692	2013, RE-Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436693	2013, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 350/13/61, DACO: 2.11.4,2.12 CBI
2436694	2014, D101698-117. 1H NMR of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436695	2012, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436696	2012, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 112/12/61, DACO: 2.11.4,2.12 CBI
2436697	2013, [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436698	2011, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436699	2011, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 145/11/61, DACO: 2.11.4,2.12 CBI
2436700	2011, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436701	2011, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 152/11/61, DACO: 2.11.4,2.12 CBI
2436702	2010, Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436703	2010, Study Data Package Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436704	2013, RE-Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436705	2013, Determination of organic impurities by [CBI REMOVED]Primary and secondary data GLP Study No.: 171/13/61, DACO: 2.11.4,2.12 CBI
2436707	2010, 1H NMR Spectrum of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436708	2009, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436709	2009, Annexure 2 Results of Analysis on Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436710	2012, RE-Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436712	2012, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 51/12/61, DACO: 2.11.4,2.12 CBI
2436714	2012, Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436717	2012, Study Data Package Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI

2436720	2012, [CBI REMOVED] Analytical data sheet, LC-MS report, HPLC report, NMR spectrum, DACO: 2.11.4,2.12 CBI
2436721	2012, Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436722	2012, Study Data Package Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436723	2012, [CBI REMOVED], Analytical data sheet, NMR spectrum, HPLC report, LC-MS report, DACO: 2.11.4,2.12 CBI
2436725	2012, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436726	2012, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 256/11/61, DACO: 2.11.4,2.12 CBI
2436727	2013, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436728	2013, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 316/12/61, DACO: 2.11.4,2.12 CBI
2436729	2012, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436730	2012, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 3/12/61, DACO: 2.11.4,2.12 CBI
2436731	2011, Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436732	2011, Study Data Package Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436733	2013, RE-Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436734	2013, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 429/13/61, DACO: 2.11.4,2.12 CBI
2436735	2009, [CBI REMOVED]: Certificate of Analysis, NMR spectrum, HPLC report, Mass report, DACO: 2.11.4,2.12 CBI
2436736	2012, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436737	2012, Determination of organic impurities by [CBI REMOVED] Primary and secondary data GLP Study No.: 22/12/61, DACO: 2.11.4,2.12 CBI
2436738	2013, Re-Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436739	2013, Determination of organic impurities by [CBI REMOVED]Primary and secondary data GLP Study No.: 424/13/61, DACO: 2.11.4,2.12 CBI
2436740	2009, [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436741	2013, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436742	2013, Raw Data from DuPont-38287 Characterization of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436743	2013, Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436744	2013, Raw Data from DuPont-38288 Characterization Of [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436745	2013, [CBI REMOVED], DACO: 2.11.4,2.12 CBI
2436750	2014, Oxathiapiprolin DuPont Response, DACO: 2.11.4,2.12,7.8,8.2.2.2 CBI
2365162	2012, Independent laboratory validation of the residue analytical method for DPX-QGU42 and its metabolites in water as described in DuPont-32124, DACO: 8.2.2.3, Document K,IIA 4.5
2365164	2011, Analytical method for the determination of DPX-QGU42 and metabolites in water using LC/MS/MS, DACO: 8.2.2.3, Document K,IIA 4.5
2365166	2013, Analytical method for the determination of DPX-QGU42 and metabolites in water using LC/MS/MS, DACO: 8.2.2.3, Document K,IIA 4.5

2365170	2011, Independent laboratory validation of Analytical method for the determination of DPX-QGU42 and metabolites IN-E8S72, IN-QPS10, IN-RDT31 and IN-RAB06 in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2, Document K,IIA 4.4,IIA 4.6
2365173	2010, Analytical method for the determination of DPX-QGU42 and metabolites IN-E8S72, IN-QPS10, IN-RDT31 and IN-RAB06 in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2, Document K,IIA 4.4,IIA 4.6
2365174	2013, Analytical method for the determination of DPX-QGU42 and metabolites IN-E8S72, IN-QPS10, IN-RDT31 and IN-RAB06 in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2, Document K,IIA 4.4,IIA 4.6
2365214	2011, Analytical method for the determination of DPX-QGU42 in fish using LC/MS/MS, DACO: 7.2.1,7.2.4, Document K,IIA 4.3
2365216	2013, Analytical method for the determination of DPX-QGU42 in fish using LC/MS/MS, DACO: 7.2.1,7.2.4, Document K,IIA 4.3
2365048	2012, DPX-QGU42 100 g/L OD (oil dispersion formulation): Laboratory study of physical, chemical and technical properties with accelerated storage conducted in a high density polyethylene/ethylene vinyl alcohol container, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9,3.7,8.2.3.6, Document K,IIIA 2.1,IIIA 2.13,IIIA 2.15,IIIA 2.4.2,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.7.1,IIIA 2.7.3,IIIA 2.7.4,IIIA 2.8.2,IIIA 2.8.5.2,IIIA 2.8.8.2
2365052	2012, DPX-QGU42 (100 g/L OD), oil based suspension concentrate formulation: Laboratory study of flash point, autoflammability, oxidizing and explosive properties of liquids, DACO: 3.5.11,3.5.12,3.5.8, Document K,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.3.3
2365054	2013, DPX-QGU42 (oxathiapiprolin) 100 g/L OD oil dispersion formulation: Summary report of physical/chemical properties, storage stability and corrosion characteristics, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9, Document K,IIIA 2.1,IIIA 2.13,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.4.2,IIIA 2.5.2,IIIA 2.6.1,IIIA 2.7.1
2365059	2013, Validation of the analytical method for determination of DPX-QGU42 in DPX-QGU42 100 g/L OD formulation, DACO: 3.4.1, Document K,IIIA 5.2.1 CBI
2365063	2013, Determination of DPX-QGU42 in DPX-QGU42 100 g/L OD formulations, DACO: 3.4.1, Document K,IIIA 5.2.1
2365120	2013, Product identity and composition of end-use product Oxathiapiprolin 100 g/L OD, DACO: 3.2.1,3.2.2,3.3.1,3.3.2, Document K,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1 CBI
2436761	2014, Oxathiapiproloin, DuPont Response, DACO: 3.5.10,3.5.8 CBI
2365211	2013, Oxathiapiprolin (DPX-QGU42) 200 g/L SC suspension concentrate formulation: Summary report of physical/chemical properties, storage stability, and corrosion characteristics, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9, Document K,IIIA 2.1,IIIA 2.13,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.4.2,IIIA 2.5.2,IIIA 2.6.1,IIIA 2.7.1,IIIA 2.7.3
2365215	2013, Validation of the analytical method for determination of DPX-QGU42 in DPX-QGU42 200 g/L SC formulation, DACO: 3.4.1, Document K,IIIA 5.2.1 CBI

2365218	2013, Determination of DPX-QGU42 in DPX-QGU42 200 g/L SC formulations, DACO: 3.4.1, Document K,IIIA 5.2.1
2365245	2013, Product identity and composition of end-use product Oxathiapiprolin 200 g/L SC, DACO: 3.2.1,3.2.2,3.3.1,3.3.2, Document K,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.4,IIIA 1.4.5.1 CBI
2365247	2013, DPX-QGU42 20SC (200 g/Liter) suspension concentrate formulation: Laboratory study of flash point, autoflammability, oxidizing and explosive properties of liquids, DACO: 3.5.11,3.5.12,3.5.8, Document K,IIIA 2.2.1,IIIA 2.2.2,IIIA 2.3.1,IIIA 2.3.3
2365249	2013, Oxathiapiprolin (QGU42) 200 g/L flowable concentrate for seed treaent (FS) Formulation : Laboratory study of physical and chemical properties, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9,3.7,8.2.3.6, Document K,IIIA 2.1,IIIA 2.13,IIIA 2.4.2,IIIA 2.5.2,IIIA 2.5.3,IIIA 2.6.1,IIIA 2.7.1,IIIA 2.7.3,IIIA 2.7.4,IIIA 2.8.2,IIIA 2.8.3.1,IIIA 2.8.3.2,IIIA 2.8.5.2,IIIA 2.8.8.2

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PMRA Document Number	Reference
2364995	2013, IN-WR791: In vitro mammalian chromosome aberration test in human peripheral blood lymphocytes (HPBL), DACO: 4.8, Document K,IIA 5.8
2365000	2013, IN-WR791: Bacterial reverse mutation test, DACO: 4.8, Document K,IIA 5.8
2365003	2013, IN-SXS67: In vitro mammalian chromosome aberration test in human peripheral blood lymphocytes (HPBL), DACO: 4.8, Document K,IIA 5.8
2365007	2013, IN-SXS67: Bacterial reverse mutation assay, DACO: 4.8, Document K,IIA 5.8
2365011	2013, IN-RDT31: In vitro mammalian chromosome aberration test in human peripheral blood lymphocytes (HPBL), DACO: 4.8, Document K,IIA 5.8
2365013	2013, IN-RDT31: In vitro mammalian cell gene mutation test (CHO/HGPRT assay), DACO: 4.8, Document K,IIA 5.8
2365015	2013, IN-RDT31: Bacterial reverse mutation assay, DACO: 4.8, Document K,IIA 5.8
2365017	2013, IN-RAB06: In vitro mammalian cell gene mutation test (CHO/HGPRT assay), DACO: 4.8, Document K,IIA 5.8
2365019	2013, IN-RAB06: Bacterial reverse mutation test, DACO: 4.8, Document K,IIA 5.8
2365023	2013, IN-RAB06: In vitro mammalian chromosome aberration test in human peripheral blood lymphocytes, DACO: 4.8, Document K,IIA 5.8
2365026	2013, IN-E8S72: Repeated-dose oral toxicity 28-day feeding study in rats, DACO: 4.8, Document K,IIA 5.8
2365029	2013, IN-E8S72: In vitro mammalian chromosome aberration test in human peripheral blood lymphocytes (HPBL), DACO: 4.8, Document K,IIA 5.8
2365032	2012, IN-E8S72: In vitro mammalian cell gene mutation test (CHO/HGPRT assay), DACO: 4.8, Document K,IIA 5.8
2365035	2013, IN-E8S72: Mouse bone marrow micronucleus test, DACO: 4.8, Document K,IIA 5.8

2365036	2012, IN-E8S72: Bacterial reverse mutation test, DACO: 4.8, Document K,IIA 5.8
2365038	2010, DPX-QGU42 technical: Acute oral neurotoxicity study in rats, DACO: 4.5.12, Document K,IIA 5.7.1
2365041	2013, DPX-QGU42: H295R steroidogenesis assay, DACO: 4.8, Document K,IIA 5.6.9
2365043	2012, DPX-QGU42 technical: 5-Day uterotrophic assay for detecting endocrine activity, DACO: 4.8, Document K,IIA 5.6.9
2365045	2012, DPX-QGU42 technical: 15-Day intact male assay for detecting endocrine activity, DACO: 4.8, Document K,IIA 5.6.9
2365046	2012, DPX-QGU42 technical: An oral (gavage) prenatal developmental toxicity study in rabbits, DACO: 4.5.3, Document K,IIA 5.6.11
2365049	2013, DPX-QGU42 technical: Developmental toxicity study in rats, DACO: 4.5.2, Document K,IIA 5.6.10
2365053	2013, DPX-QGU42 technical: Multigeneration reproduction study in rats, DACO: 4.5.1, Document K,IIA 5.6.1
2365065	2013, DPX-QGU42 technical: Multigeneration reproduction study in rats, DACO: 4.5.1, Document K,IIA 5.6.1
2365068	2011, A dietary range-finding one-generation reproductive toxicity study of DPX-QGU42 technical in rats, DACO: 4.5.1, Document K,IIA 5.6.1
2365081	2013, DPX-QGU42 technical: Oncogenicity 18-month feeding study in mice, DACO: 4.4.3, Document K,IIA 5.5.3
2365088	2013, DPX-QGU42 technical: Combined chronic toxicity/oncogenicity study 2-year feeding study in rats, DACO: 4.4.1,4.4.2,4.4.4, Document K,IIA 5.5.1,IIA 5.5.2
2365099	2010, DPX-QGU42 technical: Mouse bone marrow micronucleus test, DACO: 4.5.7, Document K,IIA 5.4.4
2365101	2010, DPX-QGU42 technical: In vitro mammalian cell gene mutation test (CHO/HGPRT assay), DACO: 4.5.5, Document K,IIA 5.4.3
2365103	2010, DPX-QGU42 technical: In vitro mammalian chromosome aberration test, DACO: 4.5.6, Document K,IIA 5.4.2
2365106	2011, DPX-QGU42 technical: Bacterial reverse mutation test, DACO: 4.5.4, Document K,IIA 5.4.1
2365108	2012, DPX-QGU42 technical: 28-Day repeat dermal application study in rats, DACO: 4.3.5, Document K,IIA 5.3.7
2365113	2013, DPX-QGU42 technical: Chronic oral toxicity one-year feeding study in beagle dogs, DACO: 4.3.2, Document K,IIA 5.3.4
2365117	2012, DPX-QGU42 technical: Subchronic oral toxicity ninety-day feeding study in beagle dogs, DACO: 4.3.2, Document K,IIA 5.3.3
2365119	2013, DPX-QGU42 technical: Subchronic oral toxicity ninety-day feeding study in beagle dogs, DACO: 4.3.2, Document K,IIA 5.3.3
2365122	2011, DPX-QGU42 technical: Subchronic toxicity 90-day feeding study in rats, DACO: 4.3.1,4.5.13, Document K,IIA 5.3.2,IIA 5.7.4
2365124	2012, DPX-QGU42 technical: Subchronic toxicity 90-day feeding study in mice, DACO: 4.3.1, Document K,IIA 5.3.2
2365127	2011, DPX-QGU42 technical: Repeated-dose oral toxicity 28-day feeding study in mice, DACO: 4.3.3, Document K,IIA 5.3.1

2365128	2013, DPX-QGU42 technical: Repeated-dose oral toxicity 28-day feeding study in mice, DACO: 4.3.3, Document K,IIA 5.3.1
2365130	2010, DPX-QGU42 technical: 28-Day oral palatability study in dogs, DACO: 4.3.3, Document K,IIA 5.3.1
2365132	2010, DPX-QGU42 technical: 28-Day oral palatability study in dogs, DACO: 4.3.3, Document K,IIA 5.3.1
2365135	2010, DPX-QGU42 technical: Repeated-dose oral toxicity 28-day feeding study in rats, DACO: 4.3.3, Document K,IIA 5.3.1
2365137	2011, DPX-QGU42 technical: Repeated-dose oral toxicity 28-day feeding study in rats, DACO: 4.3.3, Document K,IIA 5.3.1
2365139	2008, 2-Week repeat dose oral gavage - IN-QGU42-020, DACO: 4.3.3, Document K,IIA 5.3.1
2365141	2010, DPX-QGU42 technical: Dermal sensitization - Magnusson-Kligman maximization method, DACO: 4.2.6, Document K,IIA 5.2.6
2365143	2010, DPX-QGU42 technical: Primary eye irritation in rabbits, DACO: 4.2.4, Document K,IIA 5.2.5
2365145	2010, DPX-QGU42 technical: Primary skin irritation in rabbits, DACO: 4.2.5, Document K,IIA 5.2.4
2365147	2010, DPX-QGU42 technical: Inhalation median lethal concentration (LC50) study in rats, DACO: 4.2.3, Document K,IIA 5.2.3
2365149	2010, DPX-QGU42 technical: Acute dermal toxicity study in rats, DACO: 4.2.2, Document K,IIA 5.2.2
2365151	2010, DPX-QGU42 technical: Acute oral toxicity - up-and-down procedure in rats, DACO: 4.2.1, Document K,IIA 5.2.1
2365153	2012, DPX-QGU42 technical: 28-Day immunotoxicity feeding study in mice, DACO: 4.2.9,4.3.8,4.4.5,4.5.8,4.8, Document K,IIA 5.10
2365155	2013, 14C-DPX-QGU42: Disposition in male and female rats during and after multiple dose administration, DACO: 4.5.9, Document K,IIA 5.1.3
2365156	2013, 14C-DPX-QGU42: Absorption, distribution, metabolism, and elimination in the Sprague-Dawley rat, DACO: 4.5.9, Document K,IIA 5.1.1
2454559	2013, DPX-QGU42 Technical: Combined Chronic Toxicity/Oncogenicity Study 2-Year Feeding Study In Rats, DACO: 4.4.4
2454561	2014, DPX-QGU42 Technical: Multigeneration Reproduction Study in Rats, DACO: 4.5.1
2365085	2012, DPX-QGU42 100 g/L OD: *In vivo* percutaneous absorption of DPX-QGU42 in the rat, DACO: 5.8, Document K,IIIA 7.6.1
2365287	2013, Oxathiapiprolin Use description scenario, DACO: 10.1 (OECD)
2364965	2013, Metabolism of [14C]IN-SXS67 in lactating goats, DACO: 6.2, Document K,IIA 6.2.3
2364967	2011, The metabolism of [pyrazole-5-14C]DPX-QGU42 and [thiazole-5-14C]DPX-QGU42 in lettuce, DACO: 6.3, Document K,IIA 6.2.1
2364969	2011, The metabolism of [pyrazole-5-14C]DPX-QGU42 and [thiazole-5-14C]DPX-QGU42 in grapes, DACO: 6.3, Document K,IIA 6.2.1
2364973	2012, The metabolism of [pyrazole-5-14C]DPX-QGU42 and [isoxazoline-5-14C]DPX-QGU42 in potato plants following soil application at 600g a.s/ha, DACO: 6.3, Document K,IIA 6.2.1

2364976	2012, The metabolism of [pyrazole-5-14C]DPX-QGU42 and [isoxazoline-5-14C]DPX-QGU42 in lettuce plants following soil application at 600 g a.s/ha, DACO: 6.3, Document K, IIA 6.2.1
2364977	2012, The metabolism of [pyrazole-5-14C]DPX-QGU42 and [isoxazoline-5-14C]DPX-QGU42 in courgette plants following soil application at 600 g a.s./ha, DACO: 6.3, Document K, IIA 6.2.1
2364982	2013, The metabolism of [pyrazole-5-14C]-DPX-QGU42 and [thiazole-5-14C]-DPX-QGU42 in potato plants, DACO: 6.3, Document K, IIA 6.2.1
2365176	2013, Metabolism of [14C]DPX-QGU42 in the lactating goat, DACO: 6.2,7.2.1,7.2.4, Document K, IIA 4.3,IIA 6.2.3
2365178	2013, Metabolism of [14C]DPX-QGU42 in laying hens, DACO: 6.2,7.2.1,7.2.4, Document K, IIA 4.3,IIA 6.2.2
2364834	2013, Proposal of oxathiapiprolin residue definitions for crop commodities, DACO: 7.1,7.8, Document K, IIA 6.7.1
2364838	2013, Magnitude of residues of DPX-QGU42 and its metabolites in field rotational crops following applications of DPX-QGU42 100 g/L OD or DPX-QGU42 200 g/L SC - USA and Canada, 2012, DACO: 7.4.4, Document K, IIA 6.6.3
2364840	2013, Limited field crop rotation study with DPX-QGU42 100 g/L OD - NAFTA, 2011-2012, DACO: 7.4.4, Document K, IIA 6.6.3
2364848	2013, Level of oxathiapiprolin residues in rotational crops, DACO: 7.4.4, Document K, IIA 6.6.3
2364855	2013, Confined rotational crop study using [isoxazoline-5-14C]DPX-QGU42, [pyrazole-5-14C]DPX-QGU42 and [thiazole-5-14C]DPX-QGU42, DACO: 7.4.4, Document K, IIA 6.6.2
2364858	2013, Confined rotational crop study of [pyrazole-5-14C]DPX-QGU42 and [isoxazoline-5-14C]DPX-QGU42, in wheat, turnip and lettuce at 600 g a.s./ha, DACO: 7.4.4, Document K, IIA 6.6.2
2364862	2012, Magnitude of residues of DPX-QGU42 and its metabolites in processed commodities of tomato following applications of DPX-QGU42 100 g/L OD and DPX-QGU42 200 g/L SC at an exaggerated rate - USA and Canada, 2011, DACO: 7.4.5, Document K, IIA 6.5.4
2364867	2012, Magnitude of residues of DPX-QGU42 and its metabolites in processed commodities of potato and stored potato tubers following applications of DPX-QGU42 100 g/L OD and DPX-QGU42 200 g/L SC at an exaggerated rate - USA and Canada, 2011, DACO: 7.4.5, Document K, IIA 6.5.4
2364869	2012, Magnitude of residues of DPX-QGU42 and its metabolites in processed commodities of grapes following application of DPX-QGU42 100 g/L OD - Europe, 2010-2011, DACO: 7.4.5, Document K, IIA 6.5.3
2364949	2013, DPX-QGU42: Magnitude of the residue on onion (green and dry bulb), DACO: 7.4.1,7.4.2,7.4.6, Document K, IIA 6.3.3
2364953	2013, Combined decline and magnitude of residues of DPX-QGU42 and its metabolites in potato following applications of DPX-QGU42 100 g/L OD - USA and Canada, 2012, DACO: 7.4.1,7.4.2,7.4.6, Document K, IIA 6.3.2

2560903 2015, Oxathiapiprolin residue analytical concurrent fortification recoveries for crop commodities, DACO: 7.4.1,7.4.2,7.4.4,7.4.5,7.4.6, Document K, IIA 6.3.1,IIA 6.3.10,IIA 6.3.2,IIA 6.3.3,IIA 6.3.4,IIA 6.3.5,IIA 6.3.6,IIA 6.3.7,IIA 6.3.8,IIA 6.3.9,IIA 6.5.3,IIA 6.5.4,IIA 6.6.3

2560902 2015, Stability of DPX-QGU42 and metabolites in crop matrices stored frozen, DACO: 7.3, Document K, IIA 6.1.1

2567180 2012, Validation of multi-residue method DFG S 19 for the determination of DPX-QGU42 in animal matrices by LC-MS/MS, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567182 2012, Validation of a multi-residue method DFG S 19 for the determination of DPX-QGU42 in crop matrices by LC-MS/MS, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567186 2009, QuEChERS multiresidue method testing for DuPont active ingredient DPX-QGU42, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567190 2012, Method validations for the analysis of DPX-QGU42 and metabolites in various crops, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567195 2013, Method validation for the analysis of DPX-QGU42 and metabolites in various crop matrices, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567196 2013, Method validation for the analysis of DPX-QGU42 and metabolites in oily and acidic crops, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567200 2013, Independent method validation (ILV) of the multi-residue method DFG S19 for the determination of residues of DPX-QGU42 in plant matrices by LC-MS/MS, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567205 2013, Independent method validation (ILV) of the multi-residue method DFG S19 for the determination of residues of DPX-QGU42 in animal matrices by LC-MS/MS, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567207 2012, Independent laboratory validation of the residue analytical method for DPX-QGU42 and metabolites in animal tissues, milk, and eggs as described in DuPont-31138, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567208 2013, Independent laboratory validation of the method DuPont-30422 Supplement #1 for the determination of residues of DPX-QGU42 and metabolites in crop samples using LC-MS/MS, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567210 2013, Determination of the extraction efficiency of [14C]DPX-QGU42 and its metabolites using three multi-residue methods: QuEChERS (DuPont-28696), DFG S19 crop methods, (DuPont-31140) and the DFG S19 animal milk and tissue method (DuPont-31931), DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567212 2013, Determination of the extraction efficiency of [14C]DPX-QGU42 and its metabolites using a crop residue method (DuPont-30422, Supplement 1) with plant metabolism and confined rotational crop metabolism samples, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567220 2011, Analytical method for the determination of DPX-QGU42 and metabolites in crops using LC/MS/MS, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2567222 2011, Analytical method for the determination of DPX-QGU42 and metabolites in crops using LC/MS/MS, DACO: 7.2.1,7.2.4, Document K, IIA 4.3

2365224	2013, Analytical method for the determination of DPX-QGU42 and metabolites in crops using LC/MS/MS, DACO: 7.2.1,7.2.4, Document K,IIA 4.3
2365226	2012, Analytical method for the determination of DPX-QGU42 and metabolites in animal tissues, milk and eggs using LC/MS/MS, DACO: 7.2.1,7.2.4, Document K,IIA 4.3
2364875	2013, DPX-QGU42: Magnitude of the residue of ginseng, DACO: Document K,IIA 6.3.9
2364877	2013, DPX-QGU42: Magnitude of the residue on succulent peas, DACO: Document K,IIA 6.3.8
2364884	2013, DPX-QGU42: Magnitude of the residue on lettuce (head and leaf), DACO: Document K,IIA 6.3.7
2364889	2012, Combined decline and magnitude of residues of DPX-QGU42 and its metabolites in spinach (leafy vegetables) following applications of DPX-QGU42 100 g/L OD and DPX-QGU42 200 g/L SC - USA and Canada, 2011, DACO: Document K,IIA 6.3.7
2364895	2012, Combined decline and magnitude of residues of DPX-QGU42 and its metabolites in cabbage, broccoli, cauliflower (head and stem brassica vegetables) following applications of DPX-QGU42 100 g/L OD - USA and Canada, 2011, DACO: Document K,IIA 6.3.6
2364897	2013, DPX-QGU42: Magnitude of the residue on squash (summer), DACO: Document K,IIA 6.3.5
2364899	2013, DPX-QGU42: Magnitude of the residue on cucumber (field and greenhouse), DACO: Document K,IIA 6.3.5
2364906	2013, DPX-QGU42: Magnitude of the residue on cantaloupe, DACO: Document K,IIA 6.3.5
2364924	2013, Oxathiapiprolin: Relative residues in treated crops for different application parameters - Canada and the United States, DACO: Document K,IIA 6.3.10,IIA 6.3.4,IIA 6.3.5,IIA 6.3.7
2364927	2013, Combined decline and magnitude of residues of DPX-QGU42 and its metabolites in various crops following soil applications of DPX-QGU42 200 g/L SC - USA and Canada, 2011, DACO: Document K,IIA 6.3.4,IIA 6.3.5,IIA 6.3.7
2364930	2013, DPX-QGU42: Magnitude of the residue on pepper (bell and non-bell), DACO: Document K,IIA 6.3.4
2364946	2012, Combined decline and magnitude of residues of DPX-QGU42 and its metabolites in tomatoes (fruiting vegetables) following applications of DPX-QGU42 100 g/L OD and DPX-QGU42 200 g/L SC - USA and Canada, 2011, DACO: Document K,IIA 6.3.4
2436750	2014, Oxathiapiprolcin DuPont Response, DACO: 2.11.4,2.12,7.8,8.2.2.2 CBI
2365372	2013, Oxathiapiprolin Active substance Annex IIA: Section 4: Residue chemistry Summaries and assessment (Tier II - Document M-II), DACO: 12.7, Document M

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PMRA Document Number	Reference
2364770	2013, Anaerobic aquatic metabolism of [14C]-DPX-QGU42 in two water/sediment systems, DACO: 8.2.3.6, Document K,IIA 7.8.3
2364771	2012, Anaerobic aquatic metabolism of [14C]-DPX-QGU42 in two water/sediment systems, DACO: 8.2.3.6, Document K,IIA 7.8.3
2364772	2012, [14C]-DPX-QGU42: Degradability and fate in the water/sediment system, DACO: 8.2.3.6, Document K,IIA 7.8.3
2364773	2013, DPX-QGU42: Laboratory study of ready biodegradability, DACO: 8.2.3.6, Document K,IIA 7.7
2364774	2012, [14C]-IN-E8S72: Batch equilibrium experiment in five soils, DACO: 8.2.4.2, Document K,IIA 7.4.2
2364775	2012, 14C-IN-RDT31: Batch equilibrium (adsorption/desorption) in five soils, DACO: 8.2.4.2, Document K,IIA 7.4.2
2364776	2012, 14C-IN-RAB06: Batch equilibrium (adsorption/desorption) in five soils, DACO: 8.2.4.2, Document K,IIA 7.4.2
2364777	2012, 14C-IN-QPS10: Batch equilibrium (adsorption/desorption) in five soils, DACO: 8.2.4.2, Document K,IIA 7.4.2
2364778	2010, 14C-DPX-QGU42: Batch equilibrium (adsorption/desorption) in five soils, DACO: 8.2.4.2, Document K,IIA 7.4.1
2364779	2013, 14C-DPX-QGU42: Batch equilibrium (adsorption/desorption) in a soil, DACO: 8.2.4.2, Document K,IIA 7.4.1
2364803	2013, Rate of degradation of [pyrazole-5-14C]-IN-RAB06 in five aerobic soils, DACO: 8.2.3.4.2, Document K,IIA 7.2.3
2364806	2012, Rate of degradation of [14C]-IN-RAB06 in five aerobic soils, DACO: 8.2.3.4.2, Document K,IIA 7.2.3
2364811	2013, Rate of degradation of [14C]-IN-E8S72 in five aerobic soils, DACO: 8.2.3.4.2, Document K,IIA 7.2.3
2364813	2012, Rate of degradation of 14C-IN-RDT31 in five aerobic soils, DACO: 8.2.3.4.2, Document K,IIA 7.2.3
2364815	2012, Rate of degradation of 14C-IN-QPS10 in four aerobic soils, DACO: 8.2.3.4.2, Document K,IIA 7.2.3
2364821	2013, Plant uptake of IN-E8S72, IN-RAB06 and IN-RDT31 by agricultural crops from aqueous solutions under greenhouse conditions, DACO: 8.2.3.6,8.2.4.6,8.5.1,8.6, Document K,IIA 7.13
2364823	2013, Photodegradation of [14C]-DPX-QGU42 on moist and dry soil, DACO: 8.2.3.3.1, Document K,IIA 7.1.3
2364825	2012, DPX-QGU42: Anaerobic soil metabolism, DACO: 8.2.3.4.4, Document K,IIA 7.1.2,IIA 7.2.4,IIA 7.2.5

2364827 2013, Degradation of DPX-QGU42 and its metabolites IN-RDT31, IN-RAB06, IN-Q7D41, IN-E8S72, IN-QPS10, IN-RLD51, IN-RSE01, IN-RYJ52, IN-QFD61, IN-S2K66, IN-S2K67 and difluorobenzoic acid in laboratory, field soil, and water/sediment systems, DACO: 8.2.3.4.2,8.2.3.6, Document K,IIA 7.1.1,IIA 7.2.1,IIA 7.2.3,IIA 7.3.1,IIA 7.8.3

2364830 2011, Rate of degradation of 14C-DPX-QGU42 in four aerobic soils, DACO: 8.2.3.4.2, Document K,IIA 7.1.1,IIA 7.2.1

2364832 2013, Aerobic soil metabolism of DPX-QGU42, DACO: 8.2.3.4.2, Document K,IIA 7.1.1,IIA 7.2.1

2365162 2012, Independent laboratory validation of the residue analytical method for DPX-QGU42 and its metabolites in water as described in DuPont-32124, DACO: 8.2.2.3, Document K,IIA 4.5

2365164 2011, Analytical method for the determination of DPX-QGU42 and metabolites in water using LC/MS/MS, DACO: 8.2.2.3, Document K,IIA 4.5

2365166 2013, Analytical method for the determination of DPX-QGU42 and metabolites in water using LC/MS/MS, DACO: 8.2.2.3, Document K,IIA 4.5

2365168 2012, Analytical method for determination of DPX-QGU42 in water using LC/UV, DACO: 8.2.2.3, Document K,IIA 4.5

2365169 2013, DPX-QGU42: Aerobic soil metabolism, DACO: 8.2.2.1,8.2.3.4.2, Document K,IIA 4.4,IIA 7.1.1,IIA 7.2.1

2365170 2011, Independent laboratory validation of Analytical method for the determination of DPX-QGU42 and metabolites IN-E8S72, IN-QPS10, IN-RDT31 and IN-RAB06 in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2, Document K,IIA 4.4,IIA 4.6

2365171 2010, Analytical method for the determination of DPX-QGU42 and metabolites IN-Q7D41, and IN-RAB06 in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2, Document K,IIA 4.4,IIA 4.6

2365173 2010, Analytical method for the determination of DPX-QGU42 and metabolites IN-E8S72, IN-QPS10, IN-RDT31 and IN-RAB06 in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2, Document K,IIA 4.4,IIA 4.6

2365174 2013, Analytical method for the determination of DPX-QGU42 and metabolites IN-E8S72, IN-QPS10, IN-RDT31 and IN-RAB06 in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2, Document K,IIA 4.4,IIA 4.6

2365248 2013, Calculated theoretical lifetime DPX-QGU42 in the top layer of aqueous systems, DACO: 8.2.3.3, Document K,IIA 2.9.4

2365250 2011, DPX-QGU42: Photodegradation in pH 7 buffer and natural water, DACO: 8.2.3.3,8.2.3.3.2, Document K,IIA 2.9.2,IIA 2.9.3,IIA 7.6

2365253 2010, 14C-DPX-QGU42: Laboratory study of hydrolysis as a function of pH, DACO: 8.2.3.2, Document K,IIA 2.9.1,IIA 7.5

2365304 2013, Photochemical oxidative degradation of DPX-QGU42, DACO: 8.2.3.3.3, Document K,IIA 2.10

2365091 2013, Predicted environmental concentrations of oxathiapiprolin and its metabolites in soil in Europe, DACO: 8.5, Document K,IIIA 9.4,IIIA 9.5.1,IIIA 9.5.2,IIIA 9.5.3

2365096 2013, Predicted environmental concentrations of oxathiapiprolin and its metabolites in surface water and sediment in Europe, DACO: 8.5, Document K,IIIA 9.7,IIIA 9.8.1,IIIA 9.8.2,IIIA 9.8.3,IIIA 9.8.4,IIIA 9.8.5,IIIA 9.8.6

2364621 2011, IN-RDT31: Effects on reproduction and growth of the earthworm, *Eisenia fetida*, in artificial soil with 5% peat, DACO: 9.2.3.1, Document K,IIA 8.9.1,IIA 8.9.2

2364622	2011, IN-RAB06: Effects on reproduction and growth of the earthworm, *Eisenia fetida*, in artificial soil with 5% peat, DACO: 9.2.3.1, Document K,IIA 8.9.1,IIA 8.9.2
2364626	2011, IN-QPS10: Effects on reproduction and growth of the earthworm, *Eisenia fetida*, in artificial soil with 5% peat, DACO: 9.2.3.1, Document K,IIA 8.9.1,IIA 8.9.2
2364628	2011, IN-E8S72: Effects on reproduction and growth of the earthworm, *Eisenia fetida*, in artificial soil with 5% peat, DACO: 9.2.3.1, Document K,IIA 8.9.1,IIA 8.9.2
2364630	2011, DPX-QGU42 technical: Effects on reproduction and growth of the earthworm, *Eisenia fetida*, in artificial soil with 5% peat, DACO: 9.2.3.1, Document K,IIA 8.9.1,IIA 8.9.2
2364631	2011, IN-RDT31: Effects on the collembola Folsomia candida in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364634	2011, IN-RDT31: Effects on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364637	2011, IN-RAB06: Effects on the collembola Folsomia candida in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364639	2011, IN-RAB06: Effects on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364642	2011, IN-QPS10: Effects on the collembola Folsomia candida in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364644	2011, IN-QPS10: Effects on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364645	2011, IN-E8S72: Effects on the collembola Folsomia candida in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364648	2011, IN-E8S72: Effects on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364649	2011, DPX-QGU42 technical: Effects on the collembola Folsomia candida in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364650	2012, DPX-QGU42 technical: Effects on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat, DACO: 9.2.7, Document K,IIA 8.8.2.5
2364651	2012, DPX-QGU42 100 g/L OD: An extended laboratory rate response test to study the effects on the green lacewing *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae), DACO: 9.2.5, Document K,IIA 8.8.2.4
2364652	2013, DPX-QGU42 100 g/L OD: A field study to evaluate effects on the predatory mite (Acari: Phytoseiidae) in vineyards in Germany, 2012, DACO: 9.2.5, Document K,IIA 8.8.2.2
2364654	2013, DPX-QGU42 100 g/L OD: A field study to evaluate effects on predatory mites (Acari: Phytoseiidae) in southern France, 2012, DACO: 9.2.5, Document K,IIA 8.8.2.2
2364656	2013, DPX-QGU42 100 g/L OD: A field study to evaluate effects on predatory mites (Acari: Phytoseiidae) in vineyards in Italy, 2012, DACO: 9.2.5, Document K,IIA 8.8.2.2
2364657	2012, DPX-QGU42 100 g/L OD: An extended laboratory rate response test to study the effects on the aphid parasitoid, *Aphidius rhopalosiphi* De Stefani Perez (Hymenoptera, Braconidae), DACO: 9.2.6, Document K,IIA 8.8.2.1

2364658	2011, DPX-QGU42 100 g/L OD: A laboratory test to evaluate the effects on the predatory mite, *Typhlodromus pyri* (Acari, phytoseiidae), DACO: 9.2.5, Document K,IIA 8.8.1.2
2364659	2011, DPX-QGU42 100 g/L OD: A laboratory test to study the effects on the parasitoid *Aphidius rhopalosiphi* (Hymenoptera, Braconidae), DACO: 9.2.6, Document K,IIA 8.8.1.1
2364661	2013, DPX-QGU42 100 g/L OD: A semi-field study to evaluate effects of three applications on the brood of honeybees (*Apis mellifera*; Hymenoptera, Apidae) in Phacelia tanacetifolia in Germany 2012, DACO: 9.2.4.3, Document K,IIA 8.7.4
2364663	2013, IN-WR791: Acute oral and contact toxicity to the honeybee, *Apis mellifera* L. under laboratory conditions, DACO: 9.2.4.1,9.2.4.2, Document K,IIA 8.7.1,IIA 8.7.2
2364665	2013, IN-E8S72: Acute oral contact toxicity to the honeybee, *Apis mellifera* L. under laboratory conditions, DACO: 9.2.4.1,9.2.4.2, Document K,IIA 8.7.1,IIA 8.7.2
2364666	2011, DPX-QGU42 technical: Acute oral and contact toxicity to the honeybee, *Apis mellifera* L., DACO: 9.2.4.1,9.2.4.2, Document K,IIA 8.7.1,IIA 8.7.2
2364667	2011, DPX-QGU42 technical: A 7-day static-renewal toxicity test with duckweed (*Lemna gibba* G3), DACO: 9.8.5, Document K,IIA 8.6
2364668	2013, IN-Q7D41: A prolonged sediment toxicity test with Chironomus riparius using spiked sediment, DACO: 9.9, Document K,IIA 8.5.2
2364669	2013, 14C DPX-QGU42: A prolonged sediment toxicity test with Chironomus riparius using spiked water, DACO: 9.9, Document K,IIA 8.5.2
2364670	2013, 14C DPX-QGU42: A prolonged sediment toxicity test with Chironomus riparius using spiked sediment, DACO: 9.9, Document K,IIA 8.5.2
2364672	2012, DPX-QGU42 technical: A 48-hour static acute toxicity test with Chironomus riparius, DACO: 9.9, Document K,IIA 8.5.1
2364673	2012, IN-S2K67: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364674	2012, IN-S2K66: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364675	2012, IN-RYJ52: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364676	2012, IN-RSE01: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364677	2012, IN-RDT31: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364679	2012, IN-RAB06: Effects of IN-RAB06 on growth of the green algae *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364681	2012, IN-QPS10: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364682	2012, IN-QFD61: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364685	2012, IN-Q7D41: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4
2364687	2011, IN-P3X26: Effects on the growth and growth rate of the green alga, *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4

2364689 2012, IN-E8S72: Effects of IN-E8S72 on growth of the green algae *Pseudokirchneriella subcapitata*, DACO: 9.8.2,9.8.3, Document K,IIA 8.4

2364691 2010, DPX-QGU42 technical: Effects on growth to the green algae *Pseudokirchneriella subcapitata* in a static test, DACO: 9.8.2,9.8.3, Document K,IIA 8.4

2364694 2010, DPX-QGU42 technical: Effects on growth to the blue-green algae *Anabaena flos-aquae* in a static test, DACO: 9.8.2,9.8.3, Document K,IIA 8.4

2364696 2013, DPX-QGU42 technical: A 96-hour toxicity test with the marine diatom (Skeletonema costatum), DACO: 9.8.2,9.8.3, Document K,IIA 8.4

2364698 2013, DPX-QGU42 technical: A 96-hour toxicity test with the freshwater diatom (Navicula pelliculosa), DACO: 9.8.2,9.8.3, Document K,IIA 8.4

2364699 2011, DPX-QGU42 technical: A semi-static life-cycle toxicity test with the cladoceran (*Daphnia magna*), DACO: 9.3.3, Document K,IIA 8.3.2.1

2364700 2012, DPX-QGU42 technical: A follow-through life-cycle toxicity test with the saltwater Mysid (*Americamysis bahia*), DACO: 9.3.3, Document K,IIA 8.3.2.1

2364702 2012, DPX-QGU42 technical: A 96-hour shell deposition test with the eastern oyster (*Crassostrea virginica*), DACO: 9.3.4, Document K,IIA 8.3.1.4

2364704 2011, DPX-QGU42 technical: A 96-hour static acute toxicity test with the saltwater mysid (*Americamysis bahia*), DACO: 9.3.4, Document K,IIA 8.3.1.3

2364708 2012, IN-RAB06: Acute toxicity to the cladoceran *Daphnia magna* in a static 48-hour immobilization limit test, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364709 2012, IN-E8S72: Acute toxicity to the cladoceran *Daphnia magna* in a static 48-hour immobilisation test, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364712 2011, DPX-QGU42 technical: A 48-hour static acute toxicity test with the cladoceran (*Daphnia magna*), DACO: 9.3.2, Document K,IIA 8.3.1.1

2364713 2012, Acute 48-hour toxicity test with IN-S2K67 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364715 2012, Acute 48-hour toxicity test with IN-S2K66 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364716 2012, Acute 48-hour toxicity test with IN-RYJ52 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364717 2012, Acute 48-hour toxicity test with IN-RSE01 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364718 2012, Acute 48-hour toxicity test with IN-RDT31 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364719 2012, Acute 48-hour toxicity test with IN-QPS10 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364720 2012, Acute 48-hour toxicity test with IN-QFD61 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364721 2012, Acute 48-hour toxicity test with IN-Q7D41 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364722 2011, Acute 48-hour toxicity test with IN-P3X26 to *Daphnia magna*, DACO: 9.3.2, Document K,IIA 8.3.1.1

2364723 2013, IN-S2K66: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.2

2364724 2013, IN-RYJ52: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.2

2364725	2013, IN-RSE01: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.2
2364726	2013, IN-RDT31: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.2
2364727	2013, IN-RAB06: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.2
2364728	2013, IN-QPS10: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.2
2364729	2013, IN-QFD61: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.2
2364732	2013, IN-Q7D41: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.2
2364733	2013, DPX-QGU42 technical: In vitro trout hepatocyte screen, DACO: 9.5.6, Document K,IIA 8.2.6.1
2364734	2013, DPX-QGU42 technical: A bioconcentration test with the bluegill (*Lepomis macrochirus*), DACO: 9.5.6, Document K,IIA 8.2.6.1
2364735	2012, DPX-QGU42 technical: An early life-stage toxicity test with the sheepshead minnow (*Cyprinodon variegatus*), DACO: 9.5.3.1, Document K,IIA 8.2.4
2364736	2012, DPX-QGU42 technical: An early life-stage toxicity test with the rainbow trout (*Oncorhynchus mykiss*), DACO: 9.5.3.1, Document K,IIA 8.2.4
2364737	2012, IN-RAB06: Acute toxicity of IN-RAB06 to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour static test, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364738	2012, IN-E8S72: Acute toxicity of IN-E8S72 to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour static test, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364739	2012, Acute toxicity study of IN-S2K67 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364740	2012, Acute toxicity study of IN-S2K66 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364742	2012, Acute toxicity study of IN-RYJ52 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364744	2012, Acute toxicity study of IN-RSE01 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364745	2012, Acute toxicity study of IN-RDT31 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364746	2012, Acute toxicity study of IN-QPS10 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364747	2012, Acute toxicity study of IN-QFD61 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364748	2012, Acute toxicity study of IN-Q7D41 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364749	2011, Acute toxicity study of IN-P3X26 to freshwater fish, *Oncorhynchus mykiss*, DACO: 9.5.2.3,9.5.2.4, Document K,IIA 8.2.1.3
2364750	2011, DPX-QGU42 technical: A 96-hour static acute toxicity test with the sheepshead minnow, DACO: 9.5.2.2,9.5.2.3, Document K,IIA 8.2.1.2
2364751	2011, DPX-QGU42 technical a 96-hour static acute toxicity test with the bluegill (*Lepomis macrochirus*), DACO: 9.5.2.2,9.5.2.3, Document K,IIA 8.2.1.2
2364752	2012, DPX-QGU42 technical: A 96-hour static acute toxicity test with the rainbow trout (*Oncorhynchus mykiss*), DACO: 9.5.2.1,9.5.2.3, Document K,IIA 8.2.1.1

2364753	2013, DPX-QGU42 technical: Toxicity to activated sludge in a respiration inhibition test (limit study), DACO: 9.9, Document K,IIA 8.15
2364754	2013, Oxathiapiprolin (DPX-QGU42) soil metabolite bioefficacy data, DACO: 9.9, Document K,IIA 8.14.1
2364755	2012, DPX-QGU42 100 g/L OD: A greenhouse study to investigate the effects on vegetative vigor of ten terrestrial plant species following foliar exposure, DACO: 9.8.4, Document K,IIA 8.12
2364756	2012, DPX-QGU42 100 g/L OD: A greenhouse study to investigate the effects on seedling emergence and growth of ten terrestrial plant species following soil exposure, DACO: 9.8.4, Document K,IIA 8.12
2364757	2013, IN-RDT31: Assessment of the effects on soil micro flora, DACO: 9.2.8,9.2.9, Document K,IIA 8.10.1,IIA 8.10.2
2364758	2012, IN-RAB06: Assessment of the effects on soil microflora, DACO: 9.2.8,9.2.9, Document K,IIA 8.10.1,IIA 8.10.2
2364759	2013, IN-QPS10: Assessment of the effects on soil micro flora, DACO: 9.2.8,9.2.9, Document K,IIA 8.10.1,IIA 8.10.2
2364760	2012, IN-E8S72: Assessment of the effects on soil microflora, DACO: 9.2.8,9.2.9, Document K,IIA 8.10.1,IIA 8.10.2
2364761	2012, DPX-QGU42 technical: Assessment of the effects on soil microflora, DACO: 9.2.8,9.2.9, Document K,IIA 8.10.1,IIA 8.10.2
2364762	2012, DPX-QGU42: A reproduction study with the northern bobwhite, DACO: 9.6.3.1,9.6.3.2,9.6.3.3, Document K,IIA 8.1.4
2364763	2012, DPX-QGU42: A reproduction study with the mallard, DACO: 9.6.3.1,9.6.3.2,9.6.3.3, Document K,IIA 8.1.4
2364764	2011, DPX-QGU42: A dietary LC50 study with the mallard, DACO: 9.6.2.6, Document K,IIA 8.1.3
2364765	2011, DPX-QGU42: A dietary LC50 study with the northern bobwhite, DACO: 9.6.2.4,9.6.2.5, Document K,IIA 8.1.2
2364766	2011, DPX-QGU42: An acute oral toxicity study with the northern bobwhite, DACO: 9.6.2.1,9.6.2.2,9.6.2.3, Document K,IIA 8.1.1
2364767	2011, DPX-QGU42: An acute oral toxicity study with the zebra finch (Poephila guttata), DACO: 9.6.2.1,9.6.2.2,9.6.2.3, Document K,IIA 8.1.1
2365098	2012, DPX-QGU42 100 g/L OD: An acute oral toxicity study with the northern bobwhite, DACO: 9.6.4, Document K,IIIA 10.1.6
2365100	2012, DPX-QGU42 100 g/L OD: A dietary LC50 study with the northern bobwhite, DACO: 9.6.4, Document K,IIIA 10.1.6
2365102	2011, DPX-QGU42 100 g/L OD: A 96-hour static acute toxicity test with the rainbow trout (*Oncorhynchus mykiss*), DACO: 9.5.4, Document K,IIIA 10.2.2.1
2365104	2010, DPX-QGU42 100 g/L OD: Static, acute, 48-hour toxicity test with the cladoceran, *Daphnia magna*, DACO: 9.3.2, Document K,IIIA 10.2.2.2
2365107	2012, DPX-QGU42 100 g/L OD: A 72-hour toxicity test with the freshwater alga (*Pseudokirchneriella subcapitata*), DACO: 9.8.2,9.8.3, Document K,IIIA 10.2.2.3
2365109	2011, DPX-QGU42 100 g/L OD: Acute oral and contact toxicity to the honeybee, *Apis mellifera* L., DACO: 9.2.8, Document K,IIIA 10.4.2.1,IIIA 10.4.2.2
2365110	2013, DPX-QGU42 100 g/L OD: Effects on reproduction and growth of the earthworm, *Eisenia fetida*, in artificial soil with 5% peat, DACO: 9.2.8, Document K,IIIA 10.6.2,IIIA 10.6.3

2365112	2013, DPX-QGU42 100 g/L OD: Effects on reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5% peat, DACO: 9.2.8, Document K,IIIA 10.6.6
2365115	2013, DPX-QGU42 100 g/L OD: Effects on the collembola Folsomia candida in artificial soil with 5% peat, DACO: 9.2.8, Document K,IIIA 10.6.6
2365116	2012, DPX-QGU42 100 g/L OD: Assessment of the effects on soil microflora, DACO: 9.2.8, Document K,IIIA 10.7.1
2365118	2013, Risk assessment for birds and mammals exposed to oxathiapiprolin (DPX-QGU42) as contained in Oxathiapiprolin 100 g/L OD, DACO: 9.6.4,9.7.2, Document K,IIIA 10.1.1,IIIA 10.1.2,IIIA 10.1.9,IIIA 10.3.1.1,IIIA 10.3.1.2,IIIA 10.3.1.3
2365236	2012, DPX-QGU42 200 g/L SC: Acute oral and contact toxicity to the honeybee, *Apis mellifera* L., DACO: 9.2.8, Document K,IIIA 10.4.2.1,IIIA 10.4.2.2
2365238	2013, DPX-QGU42 200 g/L SC: Effects on reproduction and growth of the earthworm, *Eisenia fetida*, in artificial soil with 5% peat, DACO: 9.2.8, Document K,IIIA 10.6.2,IIIA 10.6.3

4.0 Value

PMRA Document Number	Reference
2365123	2013, Biological Assessment Dossier For DPX-QGU42 100 OD AND DPX-QGU42 200 SC - Canada, DACO: 10.1 (OECD),10.2.3.1,10.3.1,10.3.1 (OECD),12.7, Document M,IIIA 6.6
2436773	2014, Oxathiapiproloin, DuPont Response, DACO: 10.2.3,3.5.10,3.5.8
2442953	2014, General trial data, DACO: 10.2.3.3(D)
2442954	Pest Management Centre, 2014, AAFC11-055E-126 Tolerance to, and Efficacy of DPX-QGU42 against *Phytophthora* spp. in North American Ginseng, DACO: 10.2.3.3(D)

B. Additional Information Considered

i) Published Information

1.0 Environment

Reference

Atkins E.L., Kellum D., and Atkins K.W. 1981. Reducing Pesticide Hazards to HoneyBees: Mortality prediction techniques and integrated management strategies. Univ. Calif., Div. Agric. Sci. Leaflet 2883.

Cohen, S.Z., Creeger, S.M., Carsel, R.F., Enfield, C.G. 1984. Potential for pesticide contamination of groundwater resulting from agricultural uses. In: Krueger, R. F. And J.N. Seiber (eds.), Treatment and Disposal of Pesticide Wastes. Am. Chem. Soc., Washington, DC. ACS Symp. Ser. 259. pp. 297-325.

Crailsheim, K., Schneider, L.H.W, Hrassnigg, N., Bühlmann, G., Brosch, U.; Gmeinbauer, R., and B. Schöffmann. 1992. Pollen consumption and utilization in worker honeybees (*Apis mellifera carnica*): dependence on individual age and function. J. Insect Physiol., 38 (6): 409-419.

Crailsheim, K.; Hrassnigg, N.; Gmeinbauer, R.; Szolderits, M.J.; Schneider, L.H.W. and U. Brosch. 1993. Pollen utilization in non-breeding honeybees in winter. J. Insect Physiol. 39 (5): 369-373.

Fletcher JS; Nellessen JE; Pfleeger TG. 1994. Literature review and evaluation of the EPA food chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. Environ. Toxicol. Chem. 13:1383 – 1391.

Gustafson, D.I. 1989. Groundwater ubiquity score: a simple method for assessing pesticide leachability. Environmental Toxicology and Chemistry, 8: 339–357.

Koch H. and Weisser P. 1997. Exposure of honeybees during pesticide application under field conditions. Apidologie, 28: 439-447.

Nagy, KA, 1978. Field metabolic rate and food requirement scaling in mammals and birds. Ecological Monograph. Vol.57, No.2, pp.111-128.

Rortais A., Arnold G., Halm M.P., and Touffet-Briens F. 2005. Modes of exposure of honeybees to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36: 71-83.

Briggs, G., Bromilow, R., Evans, A.A.1982. Relationships between lipophilicity and root uptake and translocation of non-ionised chemicals by barley. Pesticide Science, 13, 495-504.

Briggs, G., Bromilow, R., Evans, A., and Williams, M. 1983. Relationships between lipophilicity and the distribution of non-ionised chemicals in barley shoots following uptake by the roots. Pesticide Science, 14, 492-500.

ChemSpider, 2015. 2,6-Difluorobenzoic acid. ChemSpider ID 9413. Experimental and predicted LogP values from EPISuite, ACD/Labs, ChemAxon. http://www.chemspider.com/Chemical-Structure.9413.html.

Hoerger F; Kenaga EE., 1972. Pesticide residues on plants: correlation of representative data as basis for estimation of their magnitude in the environment. In: Coulston F; Korte F. (eds). Global aspects of chemistry, toxicology and technology as applied to the environment, Vol. I. Thieme, Stuttgart, and Academic Press, New York. pp. 9-28.

Kenaga EE., 1973. Factors to be considered in the evaluation of the toxicity of pesticides to birds in their environment. In: Coulston F; Dote F. (eds). Global aspects of chemistry, toxicology and technology as applied to the environment, Vol. II. Thieme, Stuttgart, and Academic Press, New York. pp. 166-181.

Linders J, Mensink, H., Stephenson G., Wauchope D., and Racke K. 2000. Foliar interception and retention values after pesticide application. A proposal for standardized values for environmental risk assessment (technical report). Pure Appl Chem 72 (11): 2199-2218

McCall, P.J., Laskowski, D.A., Swann, R.L. and Dishburger, H.J., 1981. Measurements of sorption coefficients of organic chemicals and their use in environmental fate analysis. In Test Protocols for Environmental Fate and Movement of Toxicants. Proceedings of AOAC Symposium, AOAC, Washington DC.

Thus, J.L.G. 1988. Determination by HPLC of the log P value of diflubenzuron and its primary metabolites. UNIROYAL 96226, File No. DIMI-52, DI-7016, Regdoc 530. Duphar B.V., The Netherlands, 56635/36/88. Unpublished. Cited in: Food and Agriculture Organization of the United Nations review for diflubenzuron (http://www.fao.org)

Urban DJ, Cook NJ., 1986. Hazard Evaluation Division, Standard Evaluation Procedure, Ecological *Risk Assessment. EPA 540/9-85-001. US EPA, Washington, DC.*

Wolf, T.M. and Caldwell, B.C., 2001. Development of a Canadian spray drift model for the determination of buffer zone distances. In Expert Committee on Weeds - Comité d'experts en malherbologie (ECWCEM), Proceedings of the 2001 National Meeting, Québec City. Sainte-Anne-de-Bellevue, Québec: ECW-CEM. Eds. D Bernier, D R A Campbell and D Cloutier, pp. 60